# **Quantifying Efficiencies Gained Through Shareable Clinical Decision Support Resources: Final Report**

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# **Executive Summary**

The process of creating and implementing clinical decision support (CDS) is often long and resource-intensive. Most healthcare systems in the United States currently create CDS from scratch without using any pre-existing scientific or technical resources (i.e., 'isolated CDS'). In 2016, the Agency for Healthcare Research and Quality (AHRQ) launched a web-based prototype platform called CDS Connect to share resources to support CDS creation and implementation. CDS created using pre-existing scientific or technical resources is called shareable CDS.

The guiding research questions for this contract were:

- Which factors and types of resources help CDS teams improve productivity or efficiency during design, development, and deployment of isolated CDS vs. shareable CDS?
- What types of artifacts on CDS Connect lead to efficiencies during CDS design, development, and deployment?
- What other resources are desirable from CDS Connect resources that can further improve efficiency in each CDS stage?

We collected data from four healthcare institutions. The four sites varied in the populations they served, settings, and informatics capabilities. This document summarizes the work performed within each of seven primary contract tasks, including task goals, methods, and results. We also summarize recommendations to promote the use of shareable resources through CDS Connect.

# **Key Findings**

- A primary finding is that CDS projects and tools vary significantly based on site, electronic health record (EHR) vendor platform, and the complexity of the clinical condition being addressed. Therefore, comparisons between CDS projects both within healthcare systems and between healthcare systems are challenging. This challenge represents an area of research that deserves further exploration.
- Within each healthcare system, the need for CDS may arise from different organizational pathways. Examples of some pathways include operations, quality improvement, and research. Each pathway has a unique approach to deciding how much time and how many staff members to dedicate to building and deploying CDS. Decisions about time and staffing must be made regardless of whether the CDS project starts from scratch or uses shareable CDS resources.
- CDS teams do not typically track time spent on individual CDS projects. They are constantly switching between CDS projects that reflect different complexities, timelines, and priorities. Still, total time and personnel are useful gauges for understanding overall effort. Comparisons of efficiencies between isolated vs. shareable CDS projects are described numerically as ranges of time and staff members rather than averages because of the differences in pathways and approaches between projects and sites.
- Trust and transparency are important aspects of sharing CDS resources. Healthcare systems are more likely to adopt an externally-developed CDS resource, for example, if there is comprehensive information about its development and history.
- The structure and level of completeness of shareable CDS will determine how much technical work remains to be done to deploy the resource. Thus, overall technical maturity of the CDS resource can likely affect its degree of sharing. CDS resources that are accompanied by value sets, implementation guides, and computable logic are more likely to increase efficiency and thus sharing between sites.
- As a platform and set of tools, CDS Connect could be enhanced by: improving the organization of information, making it easier to use technical resources to author new artifacts, making it easier to use existing artifacts, and increasing the availability of "help and documentation" resources.

#### Recommendations

Platforms for sharing CDS—

- should provide features that help users connect with other CDS teams (e.g., discussion boards).
- should support standardizing the process of designing, developing, and deploying CDS by providing detailed resources. Resources could include checklists; guides; and templates that detail workflow, team makeup, timelines, and wireframes involved in CDS creation.
- should support the process of evidence selection during CDS design by encouraging authors to include details about: (1) the evidence (e.g., clinical users, patient population); (2) the evidence source (e.g., name of body or institution that created the evidence), including a link to access the source; and (3) evidence quality (e.g., who determined evidence quality and how quality was determined).
- should support the process of updating the evidence for CDS resources by: (1) supporting updates to the evidence, best practices, and guidelines; (2) providing guides on the process of integrating research-initiated CDS tools as a permanent operational tool in the institution's EHR; and (3) providing guides about how to prioritize patient safety when deploying updates to active CDS tools.
- should provide guidance on improving the credibility of their resources. Guidance could include encouraging more information about the evidence, specification of clinical guidelines into computable logic, and testing.
- should support the deployment stage by providing details about the makeup of deployment teams, processes, and evaluation methods.
- can optimize usability by improving the availability of help resources and the organization of information. They could also improve the back-end technical capabilities to enable upload of pre-existing clinical quality language (CQL) code.

Healthcare system leaders may find this report useful because it may help them assess how to formulate and track resources for CDS projects. The methodology and findings of this report can help estimate resource requirements during different stages of CDS projects. Additionally, findings specific to building a business case for shareable CDS can help in identifying novel resources from shareable platforms such as CDS Connect to aid healthcare systems in meeting strategic needs around improving the quality of healthcare delivery.

Researchers may find this report useful because it provides a starting point to assess resource allocation for CDS projects. Future research should explore and further validate the metrics in this report and explore methods to quantify and compare the process and effort to implement CDS tools that originate from different pathways.

# 1.0 Contract Overview

Clinical decision support (CDS) is a type of health information technology (IT) that presents information at the point of care to aid clinical diagnosis and treatment planning. When implemented well, CDS is likely to improve the quality of care by effectively integrating technology with workflow at the point of care. However, the process of creating CDS is often long and costly. It may be possible to reduce these costs if individual healthcare systems have access to publicly shareable standardized CDS resources and tools that can guide and support CDS creation.

In 2016, the Agency for Healthcare Research and Quality (AHRQ) launched a web-based platform called CDS Connect. This platform enables the creation and sharing of standards-based and publicly available CDS.<sup>5</sup> CDS Connect includes a repository of publicly accessible CDS "artifacts." CDS artifacts are resources shared among CDS developers and implementers that help transform medical knowledge (e.g., clinical practice guidelines) into interoperable forms (e.g., computable logic). CDS Connect also allows individual healthcare systems to create and share CDS artifacts through the CDS Authoring Tool and application programming interfaces (APIs).

This contract had two goals: (1) investigate how shareable CDS resources fit into the CDS lifecycle involving CDS design, development, and deployment; and (2) assess whether using resources through CDS Connect quantifiably improves efficiencies in the CDS lifecycle.

#### 1.1 Overview of Contract Tasks

Data collection occurred at four healthcare systems (see Table 1). These sites demonstrated collaboration, physical closeness for site visits, and unique characteristics to ensure diversity of settings and to support generalizing the findings.

Site Number	Data collection classification	Population Characteristics	Setting	Informatics Capability
1	Primary	Pediatric and adult	Urban and rural	Nascent
2	Primary	Pediatric	Urban	Advanced
3	Secondary	Adult	Urban	Nascent
4	Secondary	Pediatric and adult	Urban	Advanced

Table 1. Characteristics of data collection sites

Contract objectives were fulfilled through seven distinct tasks:

- <u>Task 1</u> was a catchall for project administration. This included team meetings, communication between project personnel, and arranging site visits.
- <u>Task 2</u> created metrics to characterize and evaluate the processes and resources used during CDS design, development, and deployment.

<sup>&</sup>lt;sup>1</sup> HealthIT.gov. What is clinical decision support? | FAQs | Providers & Professionals | HealthIT.gov.: https://www.healthit.gov/faq/what-clinical-decision-support. Accessed September 25, 2019.

<sup>&</sup>lt;sup>2</sup> Karsh BT. Clinical practice improvement and redesign: how change in workflow can be supported by clinical decision support. AHRQ Publication No. 09-0054EF; Rockville (MD): Agency for Healthcare Research and Quality; June 2009.

<sup>&</sup>lt;sup>3</sup> Berner ES. Clinical decision support systems: state of the art. AHRQ Publication No. 09-0069EF; Rockville (MD): Agency for Healthcare Research and Quality; June 2009.

<sup>&</sup>lt;sup>4</sup> Garg AX, Adhikari NK, McDonald H, Rosas-Arellano MP, Devereaux PJ, Beyene J, Sam J, Haynes RB. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. JAMA 293(10):1223–1238. PMID: 15755945.

<sup>&</sup>lt;sup>5</sup> https://cds.ahrq.gov/cdsconnect

- <u>Task 3</u> assessed how the two primary sites designed, developed, and deployed CDS from scratch without using pre-existing and shareable resources and information (i.e., isolated CDS).
- <u>Task 4</u> and <u>Task 5</u> assessed how the primary and secondary sites used pre-existing shareable content on AHRQ's CDS Connect website to design, develop, and deploy site-specific CDS (i.e., shareable CDS).
- Task 6 assessed the usability of AHRQ's CDS Connect website.
- Task 7 created a business case for shareable CDS.

# 1.2 The CDS Lifecycle

Creating and using CDS is a complex, multi-staged process frequently referred to as the CDS lifecycle (see Figure 1). The CDS lifecycle begins with a request for CDS; continues to design, development, and deployment; and concludes with ongoing knowledge maintenance.<sup>6</sup> For this project, we focused on the three stages that would benefit the most from shareable CDS resources: design (clinical content selection), development (technical build and testing), and deployment (implementation).

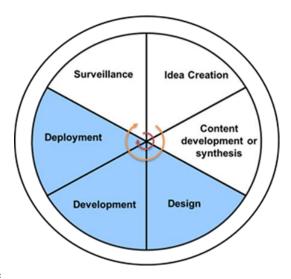


Figure 1: The CDS lifecycle

#### **Design Stage:**

The design stage involves selecting clinical content for CDS. Clinical content can include guidelines, suggestions, and rules to support diagnosis and treatment planning. Content selection or creation requires a partnership among clinicians, technical developers, and electronic health record (EHR) vendors. The content should clearly reflect the clinical goals of CDS. Clinical goals should be expressed in a format that can be translated into technical specifications.

## **Development Stage:**

The development stage involves creating technical specifications for the design, build, and testing CDS logic. The development stage requires a deep understanding of EHR elements, emerging standards, and system capabilities. According to findings from AHRQ's CDS demonstration projects, CDS development faces the challenge of reliably and efficiently converting evidence-based guidelines into a machine-readable format. There are also incompatibilities in the technical capabilities of different EHR vendors (e.g., rules, order sets, and documentation templates). Such incompatibilities translate into difficulties in implementing CDS across healthcare systems that use different EHRs.

<sup>&</sup>lt;sup>6</sup> Kannry J, Bates D, Hongsermeier T, Krall M, Yackel T. The Lifecycle of Clinical Decision Support (CDS): CDS Theory and Practice from Request to Maintenance. AMIA Annual Symposium Proceedings. 2012; 2012:3-4.

#### **Deployment Stage:**

The deployment stage involves implementing CDS and assessing its impact on outcomes through surveillance. Deployment costs may depend on the size of the healthcare system, which can vary from small clinics to large health systems. Successful implementation requires considering different factors at different stages. Prior to rollout, it is important to consider knowledge management to ensure that CDS reflects updated guidelines throughout its lifecycle. This requires planning during earlier stages of the CDS lifecycle, and coordination between clinical stakeholders (who are involved in designing evidence guidelines), development stakeholders (who manage technical updates to the CDS tool), and deployment stakeholders (who manage CDS implementation). During rollout, it is critical to customize CDS to support the local needs of end users. Customization happens by tailoring the knowledge to match the local practices of end users.

Surveillance is important in ensuring that CDS is not only usable but also useful to providers. CDS usability may be a concern when there are large variations in local workflows. It is important to monitor how CDS rollout affects clinical processes, patient outcomes, and clinical and technical performance. It is also important to make iterative changes to CDS that reflect changing recommendations and rules.

We used Boxwala and colleagues' multi-layered framework to define maturity and executability of artifacts in CDS Connect. Boxwala and colleagues' framework outlines four layers through which narrative knowledge can be transformed into executable CDS code:

- L1 (unstructured): narrative or textual guideline documents.
- L2 (semi-structured): guidelines contain structure; text describes the recommendation logic to implement CDS; clinical guidelines become fully structured by software engineers.
- L3 (structured): code readable to a computer and includes data elements, value sets, and coded logic; knowledge contains enough precision and structure to enable computation; knowledge independent of the implementation in a CDS tool or of the workflow in a clinical setting.
- L4 (executable): code readable in a CDS system at a local level; knowledge structured for use in a CDS within a clinical information system at a clinical site.

The guiding research questions for this contract included:

- Which factors and types of resources help CDS teams improve productivity or efficiency during design, development, and deployment of isolated CDS vs. shareable CDS?
- What types of artifacts on CDS Connect lead to efficiencies during CDS design, development, and deployment?
- What other resources are desirable from CDS Connect resources that can further improve efficiency in each CDS stage?

#### 2.0 Metric Selection

There were two goals in Task 2: (1) create a list of metrics to evaluate processes and resources used during the CDS lifecycle, and (2) design methods to enable collecting data from these metrics.

<sup>&</sup>lt;sup>7</sup> Boxwala, A. A., Rocha, B. H., Maviglia, S., Kashyap, V., Meltzer, S., Kim, J., Tsurikova, R., Wright, A., Paterno, MD, Fairbanks, A., & Middleton, B. (2011). A multi-layered framework for disseminating knowledge for computer-based decision support. Journal of the American Medical Informatics Association, 18(Supplement\_1), i132-i139.

#### 2.1 Methods

We used a multistage, multimethod approach to generate and refine the list of metrics. A team that was made up of experts in medicine, health IT, and human factors engineering generated the metrics. We used a modified Delphi panel to reach an agreement on the metrics. A technical expert panel further refined the metrics.

We classified the metrics as qualitative or quantitative. Qualitative metrics aligned best with the semi-structured stakeholder discussions in Tasks 3, 4, and 5. Qualitative metrics aimed at understanding processes in the CDS lifecycle. Quantitative metrics aligned best with surveys used in Tasks 3, 4, and 5. Quantitative metrics aimed to quantify effort in the CDS lifecycle. We then mapped each metric onto one or more components of the Systems Initiative in Patient Safety (SEIPS)<sup>8</sup> model (i.e., tasks, technology, person, organization, environment, process, and outcomes). SEIPS mapping ensured that we captured the context underlying each CDS stage.

## 2.2 Key Findings

We developed a total of 219 metrics (see Appendix A for the metrics list). We grouped metrics into the following categories for data collection:

- Stakeholder discussions. We created 46 qualitative metrics and 15 quantitative metrics for stakeholder discussions. Discussions included 22 metric categories (7 design, 8 development, and 7 deployment).
- Surveys. We created 63 qualitative metrics and 95 quantitative metrics for the surveys. They included 39 metric categories (15 design, 12 development, and 12 deployment).

Mapping to SEIPS elements revealed a high number of metrics assessing tasks (174 metrics), followed in frequency by technology (85 metrics), person (74 metrics), organization (61 metrics), process (42 metrics), outcomes (26 metrics), and environment (13 metrics).

We developed six unique tools to collect data through stakeholder discussion and surveys for CDS design, development, and deployment. Metric categories in the CDS design discussion guide included the following topics: team makeup, CDS specifications, guideline selection, socio-technical factors, stakeholders, patient involvement, and general factors and business case development. Metric categories in the CDS development discussion guide included the following topics: team makeup, CDS specifications, user interface, reuse, socio-technical factors, stakeholders, testing, and general factors. Metric categories in the CDS deployment discussion guide included the following topics: team makeup, implementation plan, evaluation plan, information services/information technology support, socio-technical factors, stakeholders, and general factors.

# 3.0 Isolated CDS Build (Current State) Data Collection

The goal of Task 3 was to understand and quantify the process of developing CDS from scratch without shareable resources (i.e., isolated CDS).

#### 3.1 Methods

Data were collected at the two primary sites through stakeholder discussions and surveys. Table 2 gives details about the tools and the CDS stages that data collection efforts focused on. Although Site 1 had just begun work on the continuous insulin ordering and monitoring artifact, its efforts on the enhanced recovery after surgery project were in the deployment stage. Therefore, we chose two projects from Site 1 to be able to sample all stages of the CDS lifecycle.

<sup>&</sup>lt;sup>8</sup> Carayon, P., Hundt, A. S., Karsh, B. T., Gurses, A. P., Alvarado, C. J., Smith, M., & Brennan, P. F. (2006). Work system design for patient safety: the SEIPS model. BMJ Quality & Safety, 15(suppl. 1), i50-i58.

Table 2. Focal CDS tools for data collection in Task 3

Site Number CDS stage(s)		Tool name
1	Design and development	Continuous insulin ordering and monitoring
1	Deployment	Enhanced recovery after surgery
2	Design, development, deployment	Lead screening

#### **Artifacts Overview:**

## Site 1: Insulin Ordering and Monitoring

The use of paper-based protocols, vigilance, and double checks have been recognized to be unsustainable solutions to mitigate the risks associated with continuous insulin infusion pumps. Therefore, Site 1 chose to build a CDS tool for frontline clinicians to aid ordering and monitoring of continuous insulin infusions. The tool includes reference materials to support protocol implementation, location-based order sets for dose calculation, order guidance based on the patient's clinical condition, and monitoring glucose testing. At the time of data collection, the tool was undergoing validation and usability testing focused on establishing robustness for minor protocol differences across clinical environments. Implementation of the tool was expected to change the existing clinical workflow from a manual, paper-based ordering and monitoring process to a new, semi-automated process. The new process aimed to reduce mistakes in dosing calculations, glucose testing for monitoring, and insulin rate change recommendations based on established protocols.

#### Site 1: Enhanced Recover After Surgery (ERAS)

ERAS is a recovery protocol designed to reduce a patient's length of hospital stay, narcotic use, and return to baseline function quicker than a traditional post-surgical protocol. This protocol requires multidisciplinary involvement from all levels of the patient's clinical care team (e.g., doctors, nurses, anesthesiologists) and the hospital administration. ERAS protocols have been used within Site 1 for many years. ERAS protocols have helped reduce the average post-surgical hospital stay length of colorectal patients from 7 days to 2 days. The ERAS tool, at the time of data collection, involved altering a patient's post-surgery pain management plan to exchange opioids to alternate medications. Opioids can have unintended side effects such as slowing down the digestive tract. Opioid side effects may lengthen the patient's hospital stay. Deployment of the ERAS tool consisted of familiarizing relevant stakeholders with the order set and localizing the go-live testing process at migration sites.

#### Site 2: Lead Screening

Small but clinically relevant differences exist in Federal, State, and local guideline recommendations for lead screening and management. For example, the city of Philadelphia requires two serum tests, whereas the Pennsylvania Department of Health recommends conducting risk-based assessments. Pennsylvania Medicaid requires two blood tests but suggests slightly different ages than Philadelphia guidance. Conflicting Federal guidance further complicates the picture. Handling of these differing recommendations is difficult and has resulted in poor adherence to lead management recommendations. Site 2's Lead Screening tool supports the identification and management of high blood lead levels among young children based on Centers for Disease Control and Prevention guidelines. The tool is designed to improve lead screening (to the benchmarked percentage of 89%) by improving workflow during wellness visits and simplifying the lead venous blood combination order. Tool implementation was expected to change the existing clinical workflow from a patchwork of monitoring efforts and perceived non-adherence to guidelines to a unified and evidence-based approach to identifying children with elevated lead levels in their blood.

#### **Stakeholder Discussions:**

We recruited a sample that was representative of the three stages of the CDS lifecycle: design (n=8), development (n=8), and deployment (n=8). Discussion leaders followed a semi-structured discussion guide to ask questions about topics identified in Task 2 (see Appendices D-F).

#### **Surveys:**

A subset of participants from the discussions also completed the REDCap survey (see Appendices G-L). As before, the surveys represented all three stages of the CDS lifecycle: design (n=6), development (n=3), and deployment (n=3).

#### **Site-Specific Process Maps:**

Two members of the research team observed all three stages of the CDS lifecycle at the two primary sites. The members recorded workflows, tasks, team makeup, and time requirements of CDS teams. These data were used to characterize specific tasks performed during each stage of the CDS lifecycle. We created site-specific process maps to represent the variety of pathways, teams, and timelines involved in site-specific CDS builds.

# 3.2 Key Findings

We obtained insights into variations of the process of building CDS and typical resources required to build CDS. The findings from this task also helped us better understand factors that may influence the use of shareable CDS resources.

#### Variety of CDS Pathways:

Participants from both sites reported several unique pathways to build CDS artifacts. Site 1 differentiated between CDS projects based on CDS artifact complexity (low vs. high) and the origin of the CDS request (clinician need vs. external events [e.g., regulations, strategic priorities]). Low-complexity pathways typically originated from clinicians. Clinician-initiated pathways had shorter timelines (average team calendar time = 6 months). Low-complexity pathways applied only to specific departments rather than across all departments in the institution. Higher complexity pathways began from events such as regulations or the strategic priorities of the site. These latter types of CDS projects typically affected the entire institution and required approvals from several committees. The approval process extended their team calendar time to several years.

Site 2 participants reported three distinct pathways: The quality improvement (QI) pathway, the operational pathway, and the research pathway. The QI group accepted a limited number of projects twice a year. CDS projects by the QI group were managed using a highly formalized process. Projects in the QI pathway had an accelerated timeline compared to typical CDS projects. The operational pathway is a relatively fast pathway with a timeline of sometimes just a few days. In this pathway, small teams of clinicians and developers collaborate to update a CDS project or on smaller projects to meet the operational needs of clinicians. The research pathway originates from a research team led by a principal investigator. The timelines for research pathways are longer because they require institutional review board (IRB) approval. Research-based CDS may take up to 10 years for full study completion.

Pathways across both sites differed in terms of the total calendar time (i.e., the self-reported time from initiation of the idea for the CDS artifact to completing and deploying the CDS tool). Site 2 measured operational pathway projects in weeks to months. The QI pathway that followed a series of steps took 1 to 2 months for each step. The timeline of research pathways at both sites also differed drastically from all other pathways. Site 1 participants reported that research teams conduct several rounds of design and development. Each round may involve the steps of interviews, observations, usability testing, and simulations. These steps can last an average of 1 to 5 years before design even begins on research-driven CDS tools. Site 2 also reported that idea development, applying for funding, and data collection for research-based CDS may take up to 10 years

A noticeable difference between the research pathways of the two sites was tool life after the research project. Participants at Site 2 reported that CDS tools developed for research had a finite lifespan. The limited lifespan occurred because research-based CDS tools were deactivated at the end of the research project. If deactivation did not occur, they were either handed off to information services (IS) teams or maintained and supported by the research team when appropriate. In contrast, research teams at Site 1 typically handed off the CDS tool to an operational CDS team. The operational CDS team was then responsible for management, deployment, and surveillance of the CDS tool. Research-based CDS tools built by Site 1 eventually became an operational part of the institution's EHR.

#### EHR Vendor as a Resource:

Participants frequently view the EHR vendor as a useful resource during CDS design. The most important resource provided by EHR vendors was a network to connect with CDS teams from other sites building similar tools. One design participant reported: "Epic has tools available for use and community forums to crowdsource answers to problems. We are able to look at ideas from other hospitals and modify them slightly for our system." Development stakeholders echoed this response.

The EHR vendors of both sites also contributed to CDS development. EHR vendors worked within the organization as an analyst to perform the tasks of planning, analyzing, designing, and executing changes within the EHR. Vendors also acted as an external resource by supporting requests made by the institution's developers. Another stakeholder reported: "Additional resources would be nice...particularly if there was a way to subscribe to a service provider that would help us keep up with the constant churn of guidelines."

#### **Challenges in Quantifying Effort:**

Although we attempted to elicit metrics to quantify the effort involved throughout the CDS lifecycle, we experienced several challenges that made this task difficult. First, tracking time spent working on specific projects was not reported to be a common practice among our participants. Second, despite our best efforts, we experienced limited survey response rates (sample range = 1-6 participants), in part because we could recruit only a limited number of participants due to small build teams. We were also limited in data collection procedures given our contract's time constraints and limitations associated with human subjects protections. Third, specific tasks within the CDS lifecycle are not standardized within and across sites. We found vast differences in processes to build artifacts. These differences originated from artifact complexity and the institutional priority of the artifact. In turn, the differences were reflected in terms of the number of personnel involved, and dedicated time for projects between and within different project phases and sites. Fourth, the phases of design and development sometimes overlapped, making it difficult to provide separate estimates of effort on each stage and thus obtain quantifiable differences. For this reason, we focus on reporting ranges as our primary statistic of comparison rather than averages.

Although we designed several metrics to quantify effort involved in CDS creation, time-based metrics proved to be the most valuable in actually quantifying the effort. Figure 2 illustrates these metrics. We encourage interpreting these quantitative data keeping in mind the limitations we described previously.

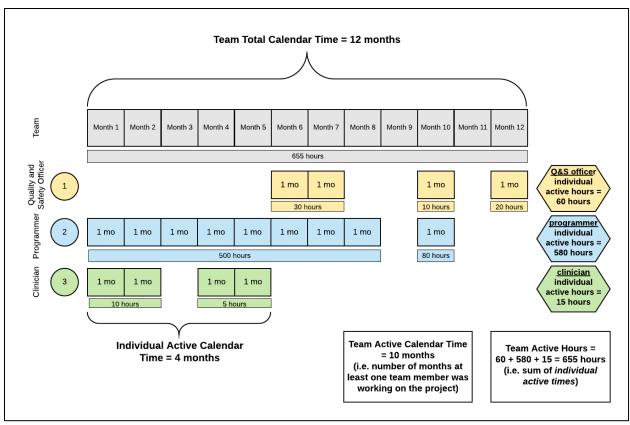


Figure 2: Example of time-based metrics to quantify individual and team time in creating CDS

The terms found in Figure 2 with their definitions are listed below:

*Individual Active Hours* – the total hours estimated by the participant as having worked on the CDS project (e.g., the Quality and Safety officer estimates <u>60 hours</u> were spent working on the CDS project).

*Individual Active Calendar Time* – the calendar period (quantified in months) that encompasses the duration of the participant's active involvement in the CDS project (e.g., the clinician estimates the 15 hours spent on the project were spread over <u>four calendar months</u>).

**Team Active Hours** – the sum of individual active hours across all team members (e.g., the sum of *individual active time* for the Quality and Safety officer, the programmer, and the clinician is 655 hours).

**Team Active Calendar Time** – the total months in which at least one team member worked on the CDS project (e.g., no team members worked on the CDS project during Months 9 and 11; thus, the team active calendar time is 10 months).

**Team Total Calendar Time** – the total calendar period (quantified in months) that encompasses the duration of all participants' involvement in the CDS project; this includes inactive time when no team members worked on the CDS project (e.g., all three team members spent various amounts of time across a 12-month period on the CDS project; thus, the team calendar time was 12 months).

An alternate way of quantifying the overall effort and duration involved in creating the CDS project in Figure 2 is 655 personnel hours over a period of 12 months. In general, team-level time metrics may be more appropriate for use by healthcare system leadership who wish to estimate total time and resource

requirements to plan CDS projects. In contrast, individual-level metrics may be more useful for project managers who wish to plan details about how much effort will be required from how many employees during each phase of the CDS lifecycle.

#### **Overall Time and Personnel Involved:**

Table 3 in Appendix B lists quantifiable resources involved in creating isolated CDS builds. There was wide variation in responses. Variations occurred because of differences in artifact complexity, site practices, and CDS phases. Differences between artifact complexity and team makeup between projects accounted for the variation in total personnel (design range = 4-12 [n=5]; development range = 12-50 [n=3]; deployment range = 2-35 [n=3]). There was also variation in the amount of involvement of team members. Less-involved team members might only be involved for 1 or 2 hours of advisement; key members and project leaders could expect to contribute weeks or months of their time.

#### **Guideline Selection and CDS Specifications:**

The tasks of guideline selection and CDS specification are part of the CDS design stage. Clinical subject matter experts (SMEs) translate clinical guidelines and determine thresholds for the specific needs of the institution. Selecting guidelines is a difficult process because it involves multiple steps: finding clinical evidence for the targeted condition, reviewing the evidence, and then synthesizing the evidence. In general, content selection and development during the design phase can take the longest time across the entire CDS lifecycle and involve the most stakeholders, especially on large projects that affect many departments and users. Perhaps because of the effort involved in guideline selection, one participant told us: "About 80 percent of CDS is developed without evidence-based resources."

#### **Testing and Iterations:**

The tasks of testing and iterative development are part of the stage of CDS development. Developers, analysts, external testing teams, and clinicians participate in development. Following each round of testing, further iterations occur to refine and correct the CDS tool. In terms of time estimation, participants reported that CDS development took between 20–80 individual active hours (n=3) and 80-500 team active hours (n=3). Technical development may take hours, but the total time for testing may run into weeks. Participants found it hard to quantify the total calendar time needed for testing because it varied widely depending on the complexity of the artifact and the number of development stage iterations.

# 4.0 Shareable CDS Resources Primary & Secondary Site Data Collection

The goal of Task 4 was to understand and quantify the process of developing CDS by using shareable CDS resources available through AHRQ's CDS Connect website.

#### 4.1 Methods

The research team collected data at the two primary sites and the two secondary sites through stakeholder discussions and surveys. We attempted to focus our investigation on artifacts of different levels of maturity. However, the selection of artifacts and the builds were entirely at the discretion of leadership at each site.

Table 4. Focal CDS tools for data collection in Task 4

Site Number	CDS Connect Artifact	Artifact Maturity <sup>7</sup>
1	Recommendation #11: Concurrent Use of Opioids and Benzodiazepines	L3 (structured)
2	Refugee Health Decision Support	L3 (structured)
3	Clostridoides Difficile (C. diff) Infection (CDI) Treatment Pathway	L2 (Semi-Structured)
4	Management of Community-Acquired Pneumonia (CAP) in Adults	L2 (Semi-Structured)

#### **Artifacts Overview:**

Table 4 gives details about the artifacts on which data collection efforts focused. All four artifacts differed on their clinical scope and complexity. We discuss artifact details and differences between artifacts below:

#### Site 1: Concurrent Use of Opioids and Benzodiazepines

The opioid crisis in the United States has brought significant attention to how health IT systems can support the care of patients at risk of harm from opioids. The goal of Site 1 was to implement evidence-based guidelines as CDS to aid in the care of patients at risk of harm from opioids in various care settings. The CDC's Recommendation #11: Concurrent Use of Opioids and Benzodiazepines is an L3 artifact that provides a recommendation to revise an opioid order when the patient is concurrently prescribed a benzodiazepine medication. This artifact supported a larger system initiative to build from an EHR vendor Opioid Toolkit with downloadable CDS tools. Implementation of the tool was expected to change the existing clinical workflow from relying on human vigilance to continuous electronic monitoring and alerting clinicians to a dangerous combination of medications.

# Site 2: Refugee Health Decision Support

Site 2 consulted with a national group of experts on refugee health to author this L3-level artifact on CDS Connect. The tool supports care and management of newly arrived refugees as per the CDC guidelines on refugee health. The development of this tool was sponsored by the CDC. At the time of data collection for the current contract, Site 2 elected to partner with an independent health care system to examine the dissemination and implementation of the Refugee Health artifact at another site. Implementation of the tool was expected to change the existing clinical workflow from inconsistent care of refugees with unique healthcare needs to standards-based evaluation and treatment of refugees across institutions according to CDC guidelines.

#### Site 3: Clostridoides Difficile (C. diff) Infection (CDI) Treatment Pathway

The C. diff artifact is an L2-level artifact that provides clinicians with recommendations to support treatment for first and recurrent CDI episodes for adults in the inpatient setting. The artifact supported a larger effort led by the infectious diseases department at Site 3 to facilitate evidence-based treatment of CDI and reduce misdiagnosis and unnecessary treatment. This effort included the development of an order validation point in the ordering process for CDI tests to decrease false positive tests caused by laxative use or recent initiation of tube feeding. A CDI diagnosis pathway, also developed at the L2 knowledge level, was also reviewed following the implementation of the treatment pathway artifact to provide comprehensive CDS for adult CDI care from diagnosis to treatment. Implementation of the tool was expected to change the existing clinical workflow from inconsistent testing and treatment of C. diff infections to the consistent evaluation and treatment of patients with C. diff and the reduction of false positive tests.

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<sup>&</sup>lt;sup>7</sup> Boxwala, A. A., Rocha, B. H., Maviglia, S., Kashyap, V., Meltzer, S., Kim, J., Tsurikova, R., Wright, A., Paterno, MD, Fairbanks, A., & Middleton, B. (2011). A multi-layered framework for disseminating knowledge for computer-based decision support. Journal of the American Medical Informatics Association, 18(Supplement\_1), i132-i139.

#### Site 4: Management of Community-Acquired Pneumonia (CAP) in Adults

Site 4 was a community, urban, walk-in hospital where CAP was an especially relevant condition identified as a priority for hospital quality improvement. This artifact is an L2 semi-structured tool that describes recommendations for CDS implementation. The CAP artifact provides resources that make it more advanced than typical L2 artifacts. The artifact provides prototypes of the CDS alert for EHRs for both the emergency department and primary care, including workflow diagrams, implementation handbook, and training content. Based on evolving methodologies of CDS creation and use, Site 4 elected to build the CAP artifact as a Fast Healthcare Interoperability Resource (FHIR) tool to integrate into their EHR. The decision to build this artifact as a FHIR tool was primarily due to the need for interoperability between multiple EHR platforms if the site decided to ultimately move to another EHR, a point of discussion over the course of this project. Implementation of the tool was expected to change the existing clinical workflow from suboptimal antibiotic choices for CAP to appropriate antibiotic selection and management of patients diagnosed with CAP in both the inpatient and ambulatory settings.

#### **Stakeholder Discussions:**

We recruited a sample that represented the three stages of the CDS lifecycle: design (n=6), development (n=4), and deployment (n=4). Discussion facilitators followed a semi-structured discussion guide to solicit information for relevant topics identified in Task 3 (see Appendices M-O).

#### Survey:

A subset of participants from the discussions also completed the REDCap survey (see Appendices P-S). As before, the survey represented all three stages of the CDS lifecycle: design (n=6), development (n=3), and deployment (n=2).

#### **Site-Specific Process Maps:**

Two members of the research team observed all three stages of the CDS lifecycle at each of the two primary sites. The goal was to record workflows, tasks, team makeup, and time requirements of CDS teams to characterize specific tasks performed during each stage of the shareable CDS lifecycle. We used data from the observations to create process maps to represent the variety of pathways, teams, and timelines involved in shareable CDS builds.

# 4.2 Key Findings

We uncovered valuable information related to trust in shareable CDS resources and artifact maturity. We first present these qualitative findings, followed by quantifiable efficiencies. We faced challenges similar to those in Task 3 when quantifying effort in Task 4. For this reason, we report ranges rather than averages. In addition, we determined that it would be inappropriate to make direct comparisons of quantifiable findings from Task 3 (isolated artifacts) and Task 4 (shareable artifacts) because of the vast differences in the nature of the CDS artifacts, as well as limited response rates on surveys.

#### **Trust in Shareable CDS Resources:**

Several participants spoke of themes related to "trust" when using artifacts on CDS Connect. One participant from an L2 artifact site reported that artifacts are useful if the user can see the coding process. An artifact that outlines the code and the reasoning behind the code can improve trust because of "the ability to show physicians the nuts and bolts behind how it could be implemented." Trust was also related to the credibility of the information in the artifacts on CDS Connect. More comprehensive and recently updated artifacts had more "trust" from clinical team members. Similarly, artifacts with more information about specifications and documentation were more likely to be "trusted" by technical team members. Participants from all sites believed that the most helpful shareable resources on any platform are those that contain already-built and coded tools from their same EHR. In summary, artifacts were helpful if they were executable, structured, and contained comprehensive information.

#### **Improving CDS Connect:**

Overall, all participants had positive impressions of artifacts on CDS Connect but also had suggestions to improve the platform. First, participants wanted more specific information (e.g., SNO-MED codes) that could lend structure to the process of creating artifacts. Second, many participants wanted the ability to contact the creators and publishers of the CDS Connect artifacts to ask questions and get additional resources. Third, participants wanted resources to aid CDS deployment. Resources could include guides on technical and user testing, metrics to capture during testing, identifying the population of end users to target for training, and tracking tool usage post-deployment.

#### **Efficiency and Artifact Maturity:**

We discovered that more mature artifacts were associated with higher efficiency. L3 artifacts, which were the most mature artifacts used in this contract, provided resources to assist with CDS criteria and workflow. L3 artifacts also provided code that was interpretable by a computer including data elements, value sets, and logic. With their credibility, L3 artifacts might allow a user to bypass the stages of design and development of a traditional CDS build. In practice, however, all participants noted the need to validate and verify the clinical and technical information provided in mature artifacts. Repeating these steps would take them back to step two (i.e., content development) of the CDS build process (see Figure 3).

The potential efficiencies offered by artifacts of different maturities are represented in Figure 3. This figure is also provided in a larger format in Appendix C.

Category	Stage 1. Idea Creation	Stage 2. Content Development	Stage 3. Design (Content Selection)	Stage 4. Development (Technical Building)	Stage 5. Deployment (Implementation)	Stage 6. Surveillance
Process	Identify issue/enhancement     Centralized, system-wide initiative Idea from front-line clinician or specialty/clinical team     Review artifacts available on CDS Connect to determine best fit between resources and need	Assign work teams from clinical specialties, clinical processes, and subject matter experts     Further define issue/enhancement/i dea/initiative     Validate resources provided in CDS artifact     Committee advisement or approval as needed before design begins	Review evidence gathered from artifact: Clinical condition Clinical users Patient population Percent of population impacted Desired patient outcomes CDS modality Clinical consensus Relevant guidelines Evaluate clinical workflow Rectify mismatching naming conventions for CDS specifications & recommendations Committee advisement or approval as needed	Utilize development resources as available in CDS artifact     Consider alert meaningfulness     Design user interface     Create test scenarios     Conduct load testing     Conduct usability testing     Multiple iterations of work between design and development during testing     Committee advisement or approval as needed	Develop implementation plan     Identify resource requirements     Identify process impact and requirements     Develop evaluation and feedback plan     Develop maintenance plan     Develop training and education plan     Go live with CDS tool     Train and educate users     Implement evaluation and maintenance plans	Ongoing active metric analysis if in implementation plan     Check-ins on usage with users and management team as necessary     Potential transfer to operations
Artifact level that can be introduced at this stage	Level 1 (Narrative Artifact)	Level 2 (Semi- structured artifact)	Level 3 (Structured Artifact) May need to revisit Stage 2 (Content Development) validate artifact information	Artifact): May need to revisit Stage 3 (Design) to localize artifact	N/A	N/A

Category	Stage 1. Idea Creation	Stage 2. Content Development	Stage 3. Design (Content Selection)	Stage 4. Development (Technical Building)	Stage 5. Deployment (Implementation)	Stage 6. Surveillance
People	Front-line clinician     Domain and content specialty teams     Institutional leadership	Clinical Advisory groups     Technical expert groups     Clinical experts/Champion     Domain & content specialty teams     Project Manager	Clinical experts/champion Technical experts EHR Analyst Clinical & technical advisory groups Project manager	Technical experts, coders, EHR analysts Clinical experts/champion Technical & IS groups Project Manager	Clinical leads/experts     Technical groups     Clinical groups     Site coordinators     Training specialists     Project manager	<ul><li>Clinical experts</li><li>Operational teams</li><li>Project manager</li></ul>
Time on Stage	Highly Variable	Variable	3-6 months	3-10 months	6-12 months	Ongoing

Figure 3: The shareable CDS pathway process map showing the efficiency gained in CDS creation based on CDS Connect artifact maturity

#### **Design Stage Findings:**

Participants envisioned shareable CDS to improve efficiency of CDS design. Specifically, participants could imagine efficiencies being gained through the availability and thoroughness of clinical evidence provided in the artifacts, especially in the more mature artifacts. For example, L3 artifacts used by Sites 1 and 2 contained descriptions of the patient population, clinical users, patient outcomes, and specific information on the recommendations, quality of evidence, and representation of the CDS. A participant reported that it would be faster to build from an L2 artifact if the artifact included more specifications and evidence. Some examples of better specifications included adding more sources of evidence and more thorough linking to references and source material for evidence: "If we (had) an L4 artifact, I could spend the day learning and save a lot of time."

Although mature shareable CDS was thought to improve efficiencies in CDS creation in theory, we found that these efficiencies were not always achieved in practice because of challenges in trusting the evidence that shareable CDS tools provide. All sites spent a lot of time verifying the credibility and validity of the evidence provided in the artifacts. Verification of the evidence and the code occurred for several reasons. First, participants wanted confirmation that the evidence originated from sources perceived as trustworthy and reputable. Second, verification ensured that the CDS reflected updated evidence. Third, verification confirmed important information such as patient population and clinical users. Fourth, verification confirmed that information matched local site workflows. For example, one site using an L3 artifact reported spending a lot of time localizing the tool to meet the specific needs of the population and the site. Fifth, verification ensured that nomenclature for CDS specifications matched the site-specific EHR and that recommendations matched the practices of the local site.

Table 5 in Appendix B presents quantifiable metrics to illustrate the differences between isolated and shareable CDS during CDS design. There was wide variation in the estimation of time during the shareable CDS design stage (individual active hours range = 15-190 [n=6]; team total calendar time = 3 months-36 months [n=3]). These variations in estimated individual effort may reflect the varied roles of our participants during CDS design. Participants included clinicians as well as developers, each of whom performed a different role on their project and spent different amounts of time on CDS design.

#### **Development Stage Findings**

Participants believed that use of shareable resources resulted in efficiencies during the development stage for several reasons. First, a match in technical specifications and codes between the shareable CDS resources and the site's EHR made it easier to use the technical files. Second, the availability of technical information in the CDS artifact served as a "head start and way to generate buy-in," which resulted in fewer delays. However, it is important to note that only the use of higher-maturity L3 tools was associated with efficiencies during CDS development. Lower-maturity L2 tools did not provide technical information to enable efficiencies during CDS development.

Participants also identified reasons why some metrics were associated with relatively small gains during the development stage for shareable CDS. First, participants spoke about artifact priority and of the difference between the team active calendar time (i.e., the total months in which at least one team member spent time on the project) vs. the total team calendar time (i.e., active time plus time spent waiting for the project to progress to the next step). Participants reported that the total time would likely be more than the active time for CDS projects designated as low-priority for the institution. For example, one site building an L2 artifact reported that even though their team had spent 22 hours on hands-on work, the total development time of the project was more than a month because of idle time waiting in a queue. Second, participants reported that even though some efficiencies increased using shareable CDS resources, it was difficult to translate these efficiencies to testing. It was difficult to obtain efficiencies during testing because the testing process followed rigorous policies set by the institution. The shareable CDS tool did not contain any resources to support testing. Even if such resources existed, the institutions' policies regarding robust testing may not have changed the overall time spent on testing.

There was wide variation in the individual active hours (range = 12-100 hours [n=3]), team active hours (range = 22-350 [n=3]), and duration of development stage iterations (range = 8 days-2 months [n=2]) for the shareable CDS. Variations in artifact complexity, maturity, and site-specific processes accounted for these wide variations. Despite these variations, we found that shareable CDS offered efficiencies in terms of team active hours (shareable CDS range = 22-350 hours [n=3]; isolated CDS range = 80-500 hours [n=3]) and team active hours during iterations (shareable CDS range = 1-25 hours [n = 3]; isolated CDS = 100 hours [n=1]). Table 6 in Appendix B presents quantifiable metrics to illustrate the differences between isolated and shareable CDS for the development stage. As before, we encourage interpreting these quantitative data keeping in mind the variations in the nature of the isolated and shareable artifacts investigated in this project.

# **Deployment Stage Findings**

In general, it was difficult to get metrics to compare isolated and shareable CDS in the deployment stage. Many tools were in the early stages of deployment at the time of data collection. Participants already reported difficulty in estimating time for the completed stages of CDS design and development and could not project how much time they needed to complete ongoing deployment efforts.

One participant from an L3 artifact site reported that, although they believed that the use of shareable CDS tools could provide time savings, they did not know which stages would benefit most. The difficulty in estimating where time saving may occur was because there were no resources to support deployment on their L3 artifact. Another participant using a different L3 artifact reported that the biggest aid was the availability of an implementation guide. However, this participant did not feel comfortable estimating specific metrics because it was their first experience using a shareable CDS artifact. Overall, we found that CDS design and development was reported to last for hours or days. However, the duration of deployment was larger and could last months.

#### **Build Team Size**

Wide variations in total personnel existed within and between sites for several reasons. First, some participants reported they did not know if the question about total personnel of the build team spanned all stages of the CDS lifecycle or individual stages of the CDS lifecycle. Second, not all team members had visibility to the entire team, so their reported number was just their perception, which could potentially undercount all possible personnel. Third, team size was partly due to the complexity of the build process at each individual site, and not the resources provided in the artifact. Fourth, not all sites had protocols to guide team assembly when using sharable CDS resources. As a result, participants reported that they assembled teams for shareable CDS using a similar process to create a team for an isolated CDS project. One site reported that their shareable CDS artifact contained information about the workflows and roles

needed at each stage of the build process, which made it easier to assemble the correct team. Stakeholders from the other three sites sought assistance in assembling a team through CDS Connect resources. They believed they may have found this assistance if they had selected an artifact at a higher level of maturity.

Despite these caveats, we found that overall, all sites used similar types of teams for creating isolated and shareable CDS builds comprising clinicians and technical team members. There were fewer technical developers on the team when the shareable CDS tool contained ready-built logic (shareable CDS development personnel range = 6-10 [n=3]) compared to isolated tools (isolated CDS development personnel range = 12-50 [n=3]) because of the information provided in the shareable tool (see Table 7 in Appendix B).

# 5.0 CDS Connect Authoring Tool and Artifact Usability Evaluation

The goal of Task 5 was to evaluate the development experience using the CDS Connect artifact repository and the CDS Connect authoring tool and provide recommendations to improve usability.

#### 5.1 Methods

We used heuristic evaluations and end-user usability evaluation to evaluate CDS Connect's artifact repository and authoring tool. Eight members of the research team conducted heuristic evaluations. The goal of a heuristic evaluation is to assess whether the design of a system matches human factors design principles and heuristics. We used heuristics for medical device evaluation published by Zhang and colleagues<sup>9</sup> (known as the Nielsen-Schneiderman Heuristics) to assess each CDS Connect platform component.

We recruited participants from all four sites to conduct usability evaluations of the CDS Connect artifact repository (n=5) and authoring tool (n=5). Participants included clinicians, clinical informaticists, and CQL developers. We used a think-aloud protocol in which participants verbalized their thoughts as they used the user interface. For every task, we captured the task number and name, goal/output, input, assumptions, steps, time, instructions for the participant, and other notes.

# 5.2 Key Findings

In general, participants reported that the CDS Connect website had a clean, consistent, and easy-to-read layout. Most participants reported that they would not have been able to build the CDS artifact on their own. However, most also reported that updating features of CDS Connect would improve the likelihood of using the platform again. For example, one participant mentioned that CDS Connect would be a good source of information when artifacts were in the nascent idea generation stage. Artifacts could be used to engage with clinicians through questions such as: "Does (the information in this tool) make sense? Would this information be helpful?" An in-depth analysis of the artifact repository and the authoring tool is detailed below.

#### **Artifact Repository:**

## Page layout and organization:

Participants in end-user usability evaluations reported that important information and resources were often located at the bottom of the page. Navigating to the desired information at the bottom of the page resulted in a lot of scrolling to locate needed information. We recommend addressing this by (1) creating a sort/filter function to enable finding desired information, (2) creating a table of contents that internally links to

<sup>&</sup>lt;sup>9</sup> Zhang, J., Johnson, T. R., Patel, V. L., Paige, D. L., & Kubose, T. (2003). Using usability heuristics to evaluate patient safety of medical devices. Journal of biomedical informatics, 36(1-2), 23-30.

sections of the webpage, and (3) re-arranging the organization of information so that useful information occurs at the top of the screen.

#### Information inconsistency:

Participants from both heuristic and usability evaluations reported inconsistency in the information contained in different artifacts. For example, there was a wide variation in the scope and comprehensiveness of the evidence included in each artifact. We recommend addressing this limitation by providing the following:

- 1. more comprehensive information for each artifact—additional information can include details about the evidence (e.g., clinical users, population), source of the evidence and link to the evidence source, evidence quality (e.g., who determined evidence quality and how quality was determined), and tools to support testing and usage of the tool;
- 2. a clear indication when the publisher/author has not given evidence information; and
- 3. a clear indication of which sections are optional.

#### Availability of help resources:

Participants reported difficulty in finding help resources. Specifically, users had questions about items on the pages (e.g., icons, definitions) when they were navigating the interface. Trying to access help resources resulted in clicking icons that wrongly appeared to be hyperlinked or clicking text expecting to find a definition but landing on a different page. Participants also reported inconsistent actions with clicking because some icons produced definitions when hovering over, not clicking. We recommend:

- 1. adding help resources on CDS Connect in addition to those contained in the "About CDS Connect" page; and
- 2. embedding help and guidance options in the artifact pages to provide in-situ assistance rather than requiring a user to click away from the artifact page.

# **Authoring Tool:**

### Authoring tool workflow:

Although participants in both evaluations had experience in health IT and CDS creation, they still reported difficulty in navigating the authoring tool. Participants reported confusion about several features. First, the purpose and definition of some sections were unclear. Second, participants did not know the order in which tasks should be performed to successfully use the authoring tool. Third, there was inconsistency in the location of the save/continue button between sections. We recommend addressing these challenges by:

- 1. improving the organization of information on the authoring tool for a more logical workflow between tool sections; and
- 2. providing guidance about the order of performing tasks in the authoring tool.

#### Availability of help resources:

Users reported difficulty in locating help information on the authoring tool. Although the "Documentation" page contains considerable help information, the title of this page did not cue users about its utility. In addition, clicking the Documentation page interrupts work because it takes users away from their task in the authoring tool. We recommend addressing these limitations by:

- 1. enhancing help resources, and
- 2. improving the availability of help resources by embedding help instructions and guidance within the authoring tool.

#### Technical resources:

Participants reported several difficulties in using the technical resources in the authoring tool. First, users reported being unable to upload pre-existing CQL into the platform. An inability to upload pre-existing code on CDS Connect resulted in duplication of work on an already-built artifact. Second, it was unclear how to use the CDS Connect platform to share artifacts. Third, the "Testing" tab does not provide a link to

Synthea to create synthetic FHIR patients. We recommend updating the back-end technical capabilities of the platform to allow for these three items to streamline the use and improve the usability of CDS Connect.

In summary, usability testing uncovered the need to put together a team to successfully use already-existing CDS artifacts or upload CDS artifacts through the authoring platform. Participants needed clinical and technical team members to transform the information in artifacts and localize it to support a site's EHR. Clinical expertise was needed to evaluate the clinical evidence of the artifacts. IT/informatics expertise was essential to navigate the logic of the CDS connect platform.

# **6.0 Business Case Development**

The goal of Task 6 was to develop a business case for creating CDS using pre-existing scientific and technical resources shared by other healthcare systems (i.e., shareable CDS) over creating CDS from scratch without the benefit of pre-existing resources (i.e., isolated CDS). Developing the business case for shareable CDS resources involves an assessment of the business problem or opportunity, cost, timescale, impact on operations, and organizational capability to deliver the project outcomes. The traditional business case development process is often organized around a five-case structure<sup>10</sup> to evaluate if an investment: (1) is supported by a compelling case for change—the strategic case, (2) optimizes value for money—the economic case, (3) is commercially viable—the commercial case, (4) is financially affordable—the financial case, and (5) is achievable—the management case. We also used the Analytic Framework for Action (AFA) <sup>11</sup> to understand how marketplace and legal factors influenced business decisions around shareable CDS.

#### 6.1 Methods

We recruited two healthcare system leadership participants from all four sites (n=8). Participants included the Chief Medical Informatics Officer (CMIO), Assistant Vice President of Information Services, Chief Quality Officer, Assistant Vice President of Pharmacy Services, and more. Each participant had deep knowledge of their institution's leadership and expertise in CDS design, development, and deployment. We used the five-case structure to guide leadership discussions. While the business case includes economic and financial components, we also include improvements in usability, corporate strategy, strategic benefits, and risks.

Each leadership discussion was led by a human factors researcher who had extensive experience in conducting interviews. Verbatim notes were taken during the interview by a notetaker. Notes under each of the five cases were thematically analyzed. Themes included ideas that captured important considerations in business case development and ideas that surfaced across multiple interviews. Although we included questions from the AFA framework to understand the marketplace and legal context of shareable CDS, the AFA did not emerge in key themes uncovered during our interviews. Therefore, we present key findings organized by the five-case structure.

# 6.2 Key Findings

# **Leadership Involvement:**

Several participants reported involvement from both clinical leaders (e.g., physicians, nurses, and pharmacists) and technical leadership (e.g., EHR teams, information systems [IS], chief information officers [CIOs]). They also reported some involvement from leaders that span the clinical and technical

<sup>&</sup>lt;sup>10</sup> Smith C, Flanagan J. Making Sense of Public Sector Investments: the 'five case model' in decision making (ISBN 185775 432.8)

<sup>&</sup>lt;sup>11</sup> Patient-Centered Clinical Decision Support Learning Network's Analytic Framework for Action. <a href="https://pccds-ln.org/analytic-framework">https://pccds-ln.org/analytic-framework</a>. Accessed October 22, 2019.

realms (e.g., CMIOs and chief nursing informatics officers), and executive leadership in the organization. Clinical leaders usually participate at the start of the process of building the strategic case for shareable CDS. Involvement of clinical leaders changes, depending on which clinicians use the shareable CDS. Technical leaders are usually involved in evaluating the strategic case. Executive leaders were often involved at the prioritization stage of critical projects.

## **Strategic Case:**

Typically, the strategic case comes from leadership in IS, strategy officers, and executive operational committees. The strategic case involved assessing whether using shareable CDS matches the strategic priorities of the organization. Over the course of our project, several participants reported interest in using artifacts housed in a public repository that had been vetted by a reputable organization such as AHRQ's CDS Connect. However, participants also reported that the actual decision to use shareable CDS must align with the strategic needs of the organization. In fact, three of our four sites adopted shareable CDS to meet strategic needs of their organization. For example, Site 1 selected the opioid artifact to fill a gap in their existing opioid package. Site 3 selected the C. diff artifact to support the institution's effort of reducing misdiagnosis and unnecessary treatment. Site 4 selected the pneumonia artifact because this disease was a quality improvement priority.

Shared artifacts that explicitly state how they are designed to meet specific strategic needs (e.g., clinical priorities, regulatory mandates) may be more likely to be selected and implemented. Individuals contributing artifacts to shareable CDS platforms may wish to identify the strategic needs that may be impacted.

#### **Economic Case:**

The economic case includes finding out if using the shareable CDS improves value for money and return on investment (ROI) compared with other CDS-based needs. The cost/benefit analyses of CDS-based changes are done by leadership in IS, clinical leaders, and groups dedicated to regulatory requirements. The cost/benefit analysis involves considering technical aspects of the CDS build process, including whether the site has the resources to build the CDS natively or requires vendor support for maintenance. The analysis also includes looking into the ROI, time savings of the technical build team, maintenance of the CDS, and the amount of work required to implement the CDS.

When estimating the timing of costs and benefits, it is important to consider that benefits may come later after CDS adoption. There is a distinction between fixed costs and variable costs. Fixed costs are those that remain the same regardless of CDS use. Variable costs are costs that increase with greater quantities of CDS use. In general, using mature CDS artifacts (e.g., L3) resulted in greater savings during the development stage by requiring fewer personnel (isolated CDS personnel range = 12-50 [n=3]; shareable CDS personnel range = 6-10 [n=3]), and team active hours (isolated CDS hours range = 80-500 [n=3]; shareable CDS hours range = 22-350 [n=3]). If research funding is available to support the build process, the economic case is improved as it is easier to assign resources towards the project. Funding may also come from the operational budget of the healthcare system. Participants explained the re-evaluation of the economic case occurred from time to time in most organizations. Re-evaluations could also happen before any major changes such as organizational restructuring or a change in investment sources.

#### **Commercial Case:**

The commercial case involves determining the commercial viability of creating shareable CDS. One of the precursors to successful commercialization is adequate testing. AHRQ's CDS Connect platform can help commercialization efforts by helping locate other sites to conduct testing. In fact, Site 2 used the CDS Connect platform to partner with another site to test their artifact.

Several factors went into judging the commercial viability of creating shareable CDS, including the size of the population impacted by the problem, the value offered to potential clients, and the solution's uniqueness, sustainability, and impact on workflows. Other considerations revolved around the effort required to refine the product to make it marketable, marketing the product, and integrating it with the infrastructure of the client. Most participants were unfamiliar with the process involved in commercializing shareable CDS. They guessed the commercialization process began with an interest in shareable CDS through dissemination efforts in conferences. Participants believed commercialization involved ROI, legal, and marketplace analyses.

Participants noted several barriers to commercialization, including academic barriers, resource barriers, legal barriers, and marketplace barriers. The biggest academic barrier was a lack of interest in monetizing the CDS. Instead, they noted a preference to offer the CDS as an open-source tool to improve provider workflow and patient care. Dissemination rather than commercialization was the route to tenure-track career growth in academic institutions. However, CDS Connect grants authors the opportunity to offer novel CDS design and logic as a form of service to the academic field and as an alternative to other dissemination methods such as peer-reviewed publications.

Participants mentioned marketplace factors as barriers to commercialization. These barriers included a lengthy development period until the product reaches the market, competing with companies that build commercial shareable CDS, and development of CDS tools that catered to a niche clinical problem. One participant stated commercialization was not common in hospitals. Hospitals try to distinguish themselves on the quality of patient care rather than on the basis of commercializing new technologies. Participants also mentioned the following hurdles: legal liabilities such as data security, updating CDS to meet policies and guidelines, and protection for creators against legal liabilities if the CDS is involved in a safety event. Resource barriers included insufficient technical personnel hours required for the maintenance of the shareable CDS, and insufficient budgets to purchase shareable CDS. All these barriers made it challenging to build a commercial case for shareable CDS, especially for academic healthcare systems.

Our findings demonstrate that most healthcare systems do not consider commercialization of CDS a reasonable path forward. Despite challenges in building the commercial business case, it is important to understand the reasons behind this decision. Feedback from stakeholders indicate that commercialization of CDS is better identified as dissemination for the purpose of career development and service to the clinical community as opposed to monetization.

#### **Financial Case:**

The financial case includes evaluating the affordability of the shareable CDS. Technical teams, clinical experts, safety experts, financial experts, and leadership calculate the financial case. The financial case is different from the economic case in that the economic case considers the opportunity cost of developing and implementing shareable CDS compared with other initiatives and needs across the entire institution. The financial case involves considerations of the institution's cash on hand and fund balances to determine the feasibility of upfront investment in using shareable CDS. Financial considerations are particularly important if there are technology costs beyond personnel time (e.g. third-party tools or required EHR upgrade) or the use of external consultants.

Financial costs are calculated by evaluating the ROI and time savings of the technical team due to the availability of resources. Costs also include maintenance of the CDS content and software, and the amount of work required to implement the shareable CDS, such as change management, implementation, and usability testing. Using shareable CDS is more affordable in the development stage because of fewer personnel (isolated CDS personnel range = 12-50 [n=3]; shareable CDS personnel range = 6-10 [n=3]), and team active hours (isolated CDS hours range = 80-500 [n=3]; shareable CDS hours range = 22-350 [n=3]).

When deciding which CDS tool to implement and weighing the use of sharable CDS versus isolated CDS, the healthcare institution will need to consider the return on investment (ROI) of the tool. Many variables may need to be considered, but the financial case is often made with consideration to improvements in safety, efficiency, meeting federal or local quality incentive programs or the ability to more accurately document and submit claims for clinical work performed. Demonstrating return on investment through quality metrics was often cited as the toughest challenge. Many variables are involved in ROI and their relative contribution to specific incentives can be difficult to calculate. All the aforementioned factors together make it difficult to show a linear relationship between use of shareable CDS and ROI. Nevertheless, measuring clinical outcomes or secondary measures such as a patients' length of stay helps in demonstrating a ROI. The financial case is often re-evaluated when projects change priority levels, require a change in scope, or are impacted by changes in federal and local incentive programs.

#### **Management Case:**

The management case comes from understanding the feasibility of using shareable CDS. In general, achievability is evaluated by knowing the existing technical capabilities of the organization. The first step is a logistical analysis of available technical resources and personnel, and evaluation of the CDS process. Second, participants perform interoperability analysis by evaluating the fit of the shareable CDS in the organization's EHR architecture, software, and hardware resources.

Several participants spoke of the need to evaluate current workflows of clinical staff expected to use the shareable CDS. Participants also mentioned the importance of an outcome analysis to understand the impact of the CDS. The impact of CDS is achieved by simulating results of shareable CDS deployment from non-production systems. The main costs used in the management case again focused on technical aspects, such as the availability of analysts and costs associated with CDS data privacy, security, and safety. The time of informatics teams is especially valuable. Additionally, the tenure of leadership plays an important role in building a management case. Turnover in leadership may affect the achievability of shareable CDS. Our team observed the negative impact of leadership turnover firsthand at a partner site. Benefits considered during the management case included understanding if the shareable CDS gave time savings to the technical team through plug-and-play elements or improved workflows and outcomes.

In summary, a business case for shareable CDS comes from using CDS artifacts that align with the strategic needs of the organization (e.g., clinician needs, QI needs, annual operating goals, reimbursement). The business case also comes from economic savings in time and personnel for clinical and informatics stakeholders and potential revenue streams by potentially improving reimbursements. Although the economic savings during CDS development are important, we found that stakeholders would not use the CDS tool if it did not meet an existing strategic need. Therefore, it is important to first convince users that the shareable CDS tool helps to address a current need in their organization and then describe how a mature artifact can help save technical costs associated with CDS development.

#### 7.0 Conclusions

## 7.1 Project Summary

The purpose of this contract was twofold. First, we investigated how shareable CDS resources fit into the CDS lifecycle comprising CDS design, development, and deployment. Second, we evaluated whether using shareable resources through CDS Connect was associated with quantifiable efficiencies in the CDS lifecycle. The four research sites had different EHRs and informatics capacities for CDS development and implementation. They allowed for comparison of efficiencies of shareable CDS resources within-sites and between-sites.

#### 1. Metric development

- a. We generated 219 metrics to evaluate and compare the lifecycle of isolated CDS vs. shareable CDS.
- b. Qualitative metrics were linked to processes (e.g., testing, iterations) and were primarily used in discussions.
- c. Quantitative metrics were linked to time (e.g., individual active calendar time, team active time) and resources (e.g., total personnel) and were primarily used in surveys.
- d. Time-based metrics proved to be the most valuable in quantifying the effort involved in CDS creation.

# 2. Quantifying effort in building isolated CDS

- a. There was substantial variation in the number of personnel involved, dedicated time for projects, and the duration of use of the CDS tool between and within different stages and sites. Some of these variations may depend on the pathway through which CDS originates: QI, operational needs, strategic needs, and research. QI and operational pathways had relatively faster timelines. At the end of the CDS build, one site kept research-initiated CDS in their EHR by handing it over to operations, while another site typically deactivated research-initiated CDS at the end of the research project.
- b. The process of selecting evidence for the CDS tool has many steps. Evidence selection involves gathering, reviewing, synthesizing, and translating clinical evidence into defined processes and pathways. Selecting clinical content for CDS is a long and resource-intensive process. One consequence is that a majority of CDS comes to life without evidence-based resources.
- c. Isolated build teams often used the EHR vendor online forums to find shareable CDS resources. The forums act as gateways to connect to other institutions, obtain ideas about CDS, and learn from other sites about CDS creation.

#### 3. Quantifying efforts in building CDS using shareable resources available on CDS Connect

- a. Estimation of effort during the design and development stages varied widely (we had difficulty in obtaining metrics about the deployment stage). These variations could be due to artifact complexity, maturity, and site-specific processes.
- b. Users have trust in shareable artifacts if they can see the code, the coding process, and the reasoning behind the code. Artifacts that were perceived to have higher credibility had two main attributes: (1) recent updates; and (2) comprehensive information about the evidence guidelines and the technical code.
- c. In the design stage, all sites spent a considerable amount of time verifying the credibility and validity of the evidence-based guidelines in the shareable CDS artifacts. Verification made sure the guidelines came from a trustworthy source, had updated evidence, allowed clarification of specifications and recommendations, enabled site-specific localization of recommendations, and enabled matching CDS specifications to site-specific naming conventions.
- d. Using more mature artifacts from CDS Connect led to more efficiency during CDS development (e.g., fewer team active hours).
  - i. Healthcare institutions use rigorous policies to guide CDS testing. Most participants reported that testing time cannot be reduced by anything provided in the CDS Connect artifacts. Therefore, it is difficult to translate efficiencies to the stage of testing.
- e. Overall, we found that CDS design and development was reported to last for hours or days. However, the duration of deployment was larger and could last months.

#### 4. Usability evaluations

- a. The CDS Connect website had a clean, consistent, and easy-to-read layout.
- b. Users reported that locating important information, information consistency, and availability of help resources were all difficult.
- c. Users reported that determining the workflow of the authoring tool, using technical resources, and availability of help resources on the authoring tool were also difficult.

- 5. Building a business case for shareable CDS
  - a. A business case for shareable CDS comes from explicit considerations of the strategic priorities of an institution.
  - b. Higher maturity shareable CDS might lead to reduced cost because of fewer technical personnel during the development stage.
  - c. Academic institutions did not perceive commercializing shareable CDS to be a viable venture.

#### 7.2 Recommendations

- 1. Promote connections to the larger community of CDS teams.
  - a. Several participants mentioned that they used EHR vendors to connect with other institutions to obtain ideas for new CDS projects or to benefit from others' experiences in managing problems encountered when creating CDS.
  - b. Shareable CDS platforms should provide features that help users connect with other CDS teams across the country (e.g., through discussion boards).
- 2. Create resources to support standardization of the process of designing, developing, and deploying CDS.
  - a. Several participants expressed interest in learning about ways to standardize the process of creating CDS.
  - b. Shareable CDS platforms can support this need by providing checklists, guides, and templates that detail general processes, workflows, team makeup, timelines, and wireframes involved in CDS creation. Such resources help lend greater structure to the CDS lifecycle and anticipate when and where resources can be allocated during the lifecycle. Some sites already used formalized processes to create CDS (e.g., QI-initiated CDS pathways used by Site 2) that can be a starting point for standardization efforts.
- 3. Support the process of evidence review.
  - a. The process of selecting, synthesizing, and reviewing the evidence during the design stage is lengthy and resource-intensive. Participants placed a premium on obtaining guidelines from reputable sources and reported spending considerable time in verifying guidelines.
  - b. We recommend supporting this process by including additional information about the evidence in artifacts, including details about: (1) the evidence (e.g., clinical users, population); (2) the source of the evidence (e.g., name of professional body or institution that created the evidence) and including a link to access the source; and (3) evidence quality (e.g., who determined evidence quality and how quality was determined).
- 4. Support updating the evidence base of CDS artifacts.
  - a. CDS projects that originate from research initiatives are valuable because they tend to include a comprehensive evidence base and undergo rigorous testing before they are deployed. However, Site 2 in our data reported research-initiated CDS tools were turned off at the end of the research project. One reason for this may be difficulty in maintaining the evidence base associated with the CDS tool.
  - b. Shareable CDS platforms can provide a valuable service to the CDS community by providing: (1) a venue to collate updates to the evidence, best practices, and guidelines associated with artifacts on CDS Connect; (2) guides on the process of integrating research-initiated CDS tools as a permanent operational tool in the institution's EHR; and (3) guides about how to prioritize patient safety when deploying updates to active CDS tools.
- 5. Provide resources to support the development of mature artifacts.
  - a. In general, mature artifacts were more comprehensive and were associated with greater efficiencies. Artifacts containing comprehensive information were perceived to be more credible.
  - b. Shareable CDS platforms should provide guidance on fields that can be included to expand the comprehensiveness of the evidence associated with the artifact. Detailing comprehensive information about the evidence (e.g., descriptions of the intended patient population, clinical

users, source and quality of the evidence), specification of clinical guidelines into computable logic, and testing (e.g., description of processes used for technical testing and usability testing, metrics utilized, nature of iterations) can help improve the credibility of the tool.

- 6. Provide resources to support CDS deployment.
  - a. Although some artifacts contained processes to support the stages of design and development, there were almost no resources to support the stage of deployment.
  - b. Shareable CDS platforms could support the deployment stage by providing implementation guides. Such guides can provide details about the makeup of deployment teams, the deployment process, when in the process metrics should be integrated to evaluate the overall success of deployment, guides on technical and user testing, metrics to capture during testing, identifying the population of end users to target for training, and tracking tool usage post-deployment.
- 7. Improve usability of CDS Connect.
  - a. Although participants found the CDS Connect website to have a clean and easy-to-read layout, they had several suggestions to improve the usability of the artifact repository and the authoring tool.
  - b. Shareable CDS platforms can improve usability by improving: (1) the availability of help resources and embedding help resources within webpages so users are not redirected away from their current tasks; (2) the consistency of information across artifacts; (3) information organization within artifacts so users can quickly and easily locate important information; (4) guidance on the intended workflow of using the authoring tool; and (5) the back-end technical capabilities of CDS Connect to enable upload of pre-existing CQL code, and linking to Synthea to create synthetic FHIR.
- 8. Projects can vary based on the strategic reason underlying their origin, institutional priority, the type of team members, and the type of institution, among other factors. The utilization and interpretation of metrics evaluating the CDS lifecycle should account for these differences.
- 9. Time-based metrics should differentiate between time spent actively working on the CDS project vs. inactive waiting time that is spent waiting on committee approvals. A reduction in active work time is a gain in efficiency, even if the CDS project ends up in an approval queue or is a lower priority to pass through a committee.

#### 7.3 Limitations

- 1. Challenges in meaningful comparisons: CDS builds vary significantly based on site, EHR vendor platform, and complexity of clinical condition being addressed. This introduced challenges in directly comparing builds within the isolated stage, as well as between and within the shareable stage.
- 2. Atypical processes of identifying CDS tools: Some sites began by reviewing artifacts available on CDS Connect to find the best fit between available artifacts/resources and the institution's needs. Reviewing CDS Connect to identify artifacts was reported to be an atypical process; therefore, it was not the most representative process of how their institution may naturally come to use CDS Connect.
- 3. Lack of standardized processes: Processes for designing, developing, and deploying CDS were not standardized across institutions or across different projects within the same institution. Variations were attributed to artifact maturity, differences between projects, sites, team makeups, and time waiting for approvals before being able to move forward. These factors accounted for large variations in time across the sites, which made it challenging to aggregate and compare metrics across institutions.
- 4. Limited sample size: We had a small sample of respondents, which may limit the generalizability of the results. The investigation of processes and resources required to create current isolated state CDS tools was limited to two sites and three projects. Similarly, the data on shareable CDS was limited to four sites. We also experienced low response rates, especially on the REDCap survey, despite engaging in regular communication with project leads from all four sites.
- 5. Challenges in time estimation: Tracking time and effort toward dedicated projects was an uncommon practice, which made it challenging for participants to accurately provide estimations about time

- resources. In addition, participants were occasionally unsure whether to only report time spent actively working on the project or also include inactive time spent on waiting for committee approvals in time estimations.
- 6. Overlapping CDS stages: Participants found it difficult to identify individual tasks within stages because the demarcations between the stages of design and development were not always clear.
- 7. Delayed CDS progression: Leaders and clinical and technical specialists at all four research sites reported expecting to be further into development and preparation for deployment when they selected tools for research. However, it was challenging to collect data about deployment because most tools were in the early stages of deployment when this document was written. As a result, most of the quantifiable data accurately report active time either building the CDS tool or in meetings and discussions about the tool, but not the waiting time that can significantly lengthen the true build time of a tool. Even with the potential for increased efficiency in tool creation with the use of shareable resources, individual site priorities and protocols have the potential to readjust the balance of time and keep build teams waiting for months to develop or deploy.
- 8. Sample characteristics: All research sites included in our project were large, urban, academic settings, which may have limited the external validity of comparisons. The findings were all from east coast facilities, which served as an advantage for site visits but limited the results. The four sites also represent two EHR vendors, which allowed within-site and between-site analyses but did not account for the range of EHR vendors and CDS capacities available.

### 7.4 Implications for Future Research

CDS is associated with improvement in quality and efficiency in healthcare delivery, but the appropriate way to evaluate its effectiveness remains uncertain. Most research focuses on the result of CDS such as meeting an organizational priority (e.g., patient satisfaction, safety) or a national priority (e.g., meaningful use, CMS quality initiatives). The results of this research project create a foundation by which to evaluate and quantify efficiencies in the CDS design, development, and deployment stages, focusing on the processes of implementation. This is an important contribution to the field, given that knowledge about the CDS lifecycle in operational settings remains understudied.

Clinical knowledge construction and maintenance is a challenge that leads to a huge burden of developing, managing, and updating CDS. As the knowledge base and health information technology advance, we must consider sensible, convenient, and cost-effective strategies to optimize CDS implementation. Through this project, the research team identified and tested metrics to quantify efficiencies of shareable CDS and identified socio-technical challenges that impact potential efficiencies gained.

# **Appendix A: Full List of Project Metrics**

Category	Metric		Stage: Develop	Stage: Deploy	Method: Discussion	Method: Survey
General questions	Percent completion	X	X	X	X	
General questions	Time (personnel hours, total project time)	X	X	X	X	
General questions	Business and strategic case metrics	X	X	X	X	
CDS team makeup	Personnel (total number, training, experience)	X	X	X	X	X
CDS team makeup	Committee organization	X	X	X	X	
CDS team makeup	EHR vendor engagement		X	X	X	
CDS team makeup	Total meetings; meeting duration	X	X	X		X
CDS team makeup	Total individual and team time (hours, months)	X	X	X		X
Stakeholders	Identification and engagement	X	X	X	X	
Stakeholders	Barriers and strategies	X	X	X	X	
Stakeholders	Resources (availability, cost)	X	X	X	X	
<b>Patient Involvement</b>	Identification and engagement	X			X	
Patient Involvement	Resources (availability, cost)	X			X	
Socio-Technical Factors	Clinical workflow evaluation	X	X	X	X	
Socio-Technical Factors	Environmental and organizational factors	X	X	X	X	
Socio-Technical Factors	Resources (availability, cost)	X	X	X	X	
Iterations	Total iterations and time (individual, team)	X	X	X		X
Iterations	Number and types of personnel	X	X	X		X
Iterations	Methodology (e.g., waterfall, scrum)	X	X	X		X
<b>Guideline collection</b>	Process	X				X
Guideline collection	Metrics (e.g., total time, number and types of personnel)	X				X
Guideline collection	Resources used	X				X
<b>Guideline selection</b>	Identification process	X			X	X
Guideline selection	Available resources and cost	X			X	
Guideline selection	Metrics (e.g., total time, number and types of personnel)	X				X
Guideline translation	Process	X				
Guideline translation	Metrics (e.g., total time, number and types of personnel)	X				
Guideline translation	Resources used	X				
Guideline abstraction	Process	X	X			
Guideline abstraction	Metrics (e.g., total time, number and types of personnel)	X	X			
Guideline abstraction	Resources used	X	X			
CDS specifications	User and target definitions (e.g., user, population)	X			X	
CDS specifications	Outcome determinations	X			X	
CDS specifications	CDS modality	X			X	X
CDS specifications	Linked knowledge repositories		X		X	
CDS specifications	Intra-operability		X		X	
CDS specifications	Personalization and customization		X		X	
CDS specifications	Error identification and recovery	X	X		X	
CDS modality	Process	X	X			X
CDS modality	Metrics (e.g., total time, number and types of personnel)	X	X			X
CDS modality	Resources used	X	X			X
Logic flow / Architecture	Process		X			X
Logic flow / Architecture	Metrics (e.g., total time, number and types of personnel)		X			X
Logic flow / Architecture	Resources used		X			X
Reuse	Existing tools/repository		X		X	
Reuse	Resources (availability, cost)		X		X	

Category	Metric		Stage: Develop	Stage: Deploy	Method: Discussion	Method: Survey
User Interface	Design		X		X	
User Interface	Resources (availability, cost)		X		X	
Testing	Technical and usability testing		X		X	
Testing	Resources (availability, cost)		X		X	X
Testing	Process		X			X
Testing	Testing coverage (amount of logic tested)		X			X
Testing	Test suite size (number of test cases and testing cycles)		X			X
Testing	Metrics (e.g., total time, number and types of personnel)		X			X
Applying codes	Process		X			X
Applying codes	Metrics (e.g., total time, number and types of personnel)		X			X
Applying codes	Resources used		X			X
Local task programming	Process		X			X
Local task programming	Metrics (e.g., total time, number and types of personnel)		X			X
Local task programming	Resources used		X			X
IT Support	Immediate Support			X	X	
IT Support	Long-term support			X	X	
Implementation plan	Skills and resources			X	X	
Implementation plan	Maintenance			X	X	
Implementation plan	Notification and education			X	X	
Implementation plan	Resources (availability, cost)			X	X	X
Implementation plan	Process				X	X
Implementation plan	Metrics (e.g., total time, number and types of personnel)				X	X
Evaluation plan	Individual provider reporting			X	X	
Evaluation plan	System reporting			X	X	
Usage frequency	Process			X		X
Usage frequency	Metrics (e.g., total time, number and types of personnel)			X		X
Usage frequency	Resources used			X		X
Vetting process	Process			X		X
Vetting process	Metrics (e.g., total time, number and types of personnel)			X		X
Vetting process	Resources used			X		X
Updates and iterations	Process and Schedule			X		X
Updates and iterations	Frequency of and intervals between updates/ iterations			X		X
Updates and iterations	Resources used			X		X
Unanticipated Events	Process for identification			X		X
Unanticipated Events	Time required to address			X		X
Unanticipated Events	Severity Level			X		X
Unanticipated Events	Duration of delay/set-back			X		X
Additional costs	Software costs	X	X	X		X
Additional costs	Hardware costs	X	X	X		X
Additional costs	Other costs	X	X	X		X

# **Appendix B: Results of Efficiency Metrics**

Table 3. Estimation of Resources Required in Creating Isolated CDS Artifacts

Resource	Design	Design	Development	Development	Deployment	Deployment
Resource Type	N	Range	N	Range	N	Range
Personnel	5	4 - 12 people	3	12 - 50 people	3	2 - 35 people
Individual active hours	5	1 - 70 hours	3	20 - 80 hours	3	8 - 100 hours
Total team calendar time	5	2.5 - 12 months	3	3 - 6 months	3	0.5 - 9 months
Team active hours	4	10 - 500 team hours	3	80 - 500 team hours	2	12 - 200 team hours

Table 5. Comparison of Quantifiable Metrics Between Isolated and Shareable CDS During CDS Design

Resource	Isolated CDS	Isolated CDS	Shareable CDS	Shareable CDS
Resource Type	N	Range	N	Range
Individual active hours	5	1 - 70 hours	6	15 - 190 hours
Team active hours	4	10 - 500 hours	4	5 - 500 hours
Team total calendar time	5	2.5 - 12 months	3	3 - 36 months
Total team calendar time (iterations)	3	3 - 12 months	3	0.75 - 6 months
Team active hours (iterations)	2	3 - 200 hours	3	10 - 60 hours
Individual active hours (evidence retrieval)	3	6 - 40 hours	3	1 - 5 hours
Individual active hours (evidence review)	3	4 - 10 hours	5	2 - 10 hours
Individual active hours (evidence synthesis)	3	4 - 10 hours	4	1 - 8 hours

Table 6. Comparison of Quantifiable Metrics Between Isolated and Shareable CDS During CDS Development

Resource	<b>Isolated CDS</b>	<b>Isolated CDS</b>	Shareable CDS	Shareable CDS
Resource Type	N	Range	N	Range
Individual active hours	3	20 - 80 hours	3	12 - 100 hours
Team active hours	3	80 - 500 hours	3	22 - 350 hours
Team total calendar time	3	3 - 6 months	3	3 - 10 months
Total iterations	1	10 iterations	3	1 - 10 iterations
Team active hours (iterations)	1	100 hours	3	1 - 25 hours
Individual calendar time (iterations)	2	0.25 - 2 months	2	0.25 - 2 months
Total team calendar time (iterations)	1	2 months	2	0.25 - 2 months

Table 7. Comparison of Team Sizes Between Isolated and Shareable CDS During CDS Design, Development, and Deployment

Resource	<b>Isolated CDS</b>	<b>Isolated CDS</b>	Shareable CDS	Shareable CDS
Resource Type	N	Range	N	Range
Design personnel	5	4 - 12	5	8 - 15
Development personnel	3	12 - 50	3	6 - 10
Deployment personnel	3	2 - 35	2	12 - 15

Table 8. Comparison of Team Sizes Between Isolated and Shareable CDS During CDS Design, Development, and Deployment

•	Metric; range (sample size)	Design Design		Development Development		Deployment	Deployment
Metric category		Isolated	Shareable	Isolated	Shareable	Isolated	Shareable
Individual active hours	Time (hours)	1-70 (N=5)	15-190 (N=6)	20-80 (N=3)	12-100 (N=3)	8-100 (N=3)	No data
Team active hours	Time (hours)	10-500 (N=4)	5-500 (N=4)	80-500 (N=3)	22-350 (N=3)	12-200 (N=2)	No data
Team total calendar time	Time (months)	2.5-12 (N=5)	3-36 (N=5)	3-6 (N=3)	3-10 (N=3)	0.5-9 (N=3)	6-12 (N=2)
Total numbers	Estimated total meetings attended	1-12 (N=6)	3-24 (N=5)	10-25 (N=3)	5-50 (N=3)	1-15 (N=3)	No data
Total numbers	Estimated total personnel involved	4-12 (N=5)	8-15 (N=5)	12-50 (N=3)	6-10 (N=3)	2-35 (N=3)	12-15 (N=2)
Individual active hours	Evidence retrieval	6-40 (N=3)	1-5 (N=3)	No data	10 (N=1)	N/A	N/A
Individual active hours	Internal guideline development	2-20 (N=2)	N/A	N/A	N/A	N/A	N/A
Individual active hours	Evidence review	4-10 (N=3)	2-10 (N=5)	2-10 (N=2)	50 (N=1)	N/A	N/A
Individual active hours	Evidence synthesis	4-10 (N=3)	1-8 (N=4)	N/A	N/A	N/A	N/A
Individual active hours	Guideline prioritization	1-2 (N=2)	1-3 (N=2)	N/A	N/A	N/A	N/A
Individual active hours	Determining factors	0.25-2 (N=2)	1-10 (N=3)	N/A	N/A	N/A	N/A
Individual active hours	Variable disambiguation	0.5-1 (N=2)	No data	N/A	N/A	N/A	N/A
Individual active hours	Content extraction	0.25 (N=1)	0.5-30 (N=2)	2 (N=1)	40-50 (N=2)	N/A	N/A
Individual active hours	Content clarification	0.25-5 (N=4)	1-50 (N=2)	2 (N=1)	1-50 (N=3)	N/A	N/A
Individual active hours	Content encoding	2-5 (N=)	No data	N/A	N/A	N/A	N/A
Individual active hours	Determining CDS modality	4 (N=1)	N/A	N/A	N/A	N/A	N/A
Individual active hours	Stage-level iterations	2-20 (N=3)	10-50 (N=4)	30 (N=1)	1-10 (N=3)	No data	No data
Individual active hours	Structuring recommendations	N/A	N/A	25 (N=1)	1-50 (N=3)	N/A	N/A
Individual active hours	Translating and encoding logic flow	N/A	N/A	No data	2-50 (N=3)	N/A	N/A
Individual active hours	Testing and pre-validation	N/A	N/A	10 (N=1)	1-25 (N=2)	N/A	N/A
Individual active hours	Task programming	N/A	N/A	No data	2-25 (N=2)	N/A	N/A
Individual active hours	Identifying outcomes	N/A	N/A	N/A	N/A	4 (N=1)	12 (N=1)
Individual active hours	Target processes	N/A	N/A	N/A	N/A	2 (N=1)	No data
Individual active hours	Set and evaluate goals process	N/A	N/A	N/A	N/A	No data	No data
Individual active hours	Vetting process	N/A	N/A	N/A	N/A	15-40 (N=2)	24 (N=1)
Individual active hours	Implementation plan	N/A	N/A	N/A	N/A	2-10 (N=3)	40-60 (N=2)
Individual active hours	Scheduling	N/A	N/A	N/A	N/A	No data	No data
Individual active hours	Availability of actionable data	N/A	N/A	N/A	N/A	No data	No data
Individual active hours	Vendor updates follow-up	N/A	N/A	N/A	N/A	No data	No data
Total numbers	Estimated number of iterations	3-5 (N=2)	3-15 (N=3)	10 (N=1)	1-10 (N=3)	1 (N=1)	1 (N=1)
Team active hours	Stage-level iterations (hours)	3-200 (N=2)	10-60 (N=3)	100 (N=1)	1-25 (N=3)	No data	No data
Individual active calendar time	Stage-level iterations (months)	3-12 (N=3)	0.75-6 (N=3)	0.25-2 (N=2)	0.25-2 (N=2)	0.25 (N=1)	No data
Team total calendar time	Stage-level iterations (months)	3 (N=2)	1-6 (N=3)	2 (N=1)	0.25-2 (N=2)	0.25 (N=1)	No data

No data = Did not receive responses for this metric, or responses were not quantifiable

N/A = this metric was not applicable due to already being built in the shareable CDS artifact or not used for this stakeholder group

# **Appendix C: Shareable CDS Pathways Process Map**

Category	Stage 1. Idea Creation	Stage 2. Content Development	Stage 3. Design (Content Selection)	Stage 4. Development (Technical Building)	Stage 5. Deployment (Implementation)	Stage 6. Surveillance
Process	Identify issue/enhancement     Centralized, system-wide initiative Idea from front-line clinician or specialty/clinical team     Review artifacts available on CDS Connect to determine best fit between resources and need	Assign work teams from clinical specialties, clinical processes, and subject matter experts     Further define issue/enhancement/idea/in itiative     Validate resources provided in CDS artifact     Committee advisement or approval as needed before design begins	Review evidence gathered from artifact: Clinical condition Clinical users Patient population Percent of population impacted Desired patient outcomes CDS modality Clinical consensus Relevant guidelines Evaluate clinical workflow Rectify mismatching naming conventions for CDS specifications & recommendations Committee advisement or approval as needed	Utilize development resources as available in CDS artifact     Consider alert meaningfulness     Design user interface     Create test scenarios     Conduct load testing     Conduct usability testing     Multiple iterations of work between design and development during testing     Committee advisement or approval as needed	Develop implementation plan     Identify resource requirements     Identify process impact and requirements     Develop evaluation and feedback plan     Develop maintenance plan     Develop training and education plan     Go live with CDS tool     Train and educate users     Implement evaluation and maintenance plans	Ongoing active metric analysis if in implementation plan     Check-ins on usage with users and management team as necessary     Potential transfer to operations
Artifact level that can be introduced at this stage	Level 1 (Narrative Artifact)	Level 2 (Semi-structured artifact)	Level 3 (Structured Artifact) May need to revisit Stage 2 (Content Development) validate artifact information	Level 4 (Executable Artifact): May need to revisit Stage 3 (Design) to localize artifact resources or Stage 2 (Content Development) to validate artifact information.	N/A	N/A
People	Front-line clinician     Domain and content specialty teams     Institutional leadership	<ul> <li>Clinical Advisory groups</li> <li>Technical expert groups</li> <li>Clinical experts/Champion</li> <li>Domain &amp; content specialty teams</li> <li>Project Manager</li> </ul>	<ul> <li>Clinical experts/champion</li> <li>Technical experts EHR</li> <li>Analyst Clinical &amp; technical advisory groups</li> <li>Project manager</li> </ul>	<ul> <li>Technical experts, coders, EHR analysts</li> <li>Clinical experts/champion</li> <li>Technical &amp; IS groups</li> <li>Project Manager</li> </ul>	<ul> <li>Clinical leads/experts</li> <li>Technical groups</li> <li>Clinical groups</li> <li>Site coordinators</li> <li>Training specialists</li> <li>Project manager</li> </ul>	<ul><li>Clinical experts</li><li>Operational teams</li><li>Project manager</li></ul>
Time on Stage	Highly Variable	Variable	3-6 months	3-10 months	6-12 months	Ongoing

# Appendix D: Isolated CDS Design Stakeholder Discussion Guide

### Questions pertaining to team makeup

- 1. Who are the folks involved in the CDS design process? What are their disciplines and level of expertise? How were they selected?
- 2. Is there a formal committee? How often do you meet? What does that meeting look like?

### **Questions pertaining to CDS specifications**

- 1. How do you define the clinical condition?
- 2. How do you define the clinical user?
- 3. How do you define the patient population?
- 4. Do you determine the percent of the population to be impacted?
- 5. How do you determine desired patient outcomes?
- 6. How do you define organizational outcomes?
- 7. Do you discuss the integration of quality measures?
- 8. Do you identify potential outliers?
- 9. How do you determine CDS modality?
- 10. Do you develop scenarios?
- 11. Do you modify thresholds?
- 12. Is there a process for error identification and recovery?
- 13. Are there any resources your team uses? (e.g., subscriptions, guidelines, tools, 3<sup>rd</sup> party vendors) What are the associated costs?

### Questions pertaining to guideline selection

- 1. What is the process for identifying guidelines?
- 2. Are there any resources your team uses? (e.g., subscriptions, guidelines, tools, 3<sup>rd</sup> party vendors) What are the associated costs?

#### Questions about socio-technical factors

- 1. Do you evaluate clinical workflow? How?
- 2. Do you evaluate environmental factors? Organizational factors?
- 3. Is there a process in place for surveillance of similar CDS tools in production? Removal of retired CDS?
- 4. Is there comparison for internal consistency?
- 5. Does the organization consider novel CDS development proprietary? Are there IP considerations?

# **Questions pertaining to stakeholders**

- 1. How do you identify stakeholders?
- 2. What types of barriers do you identify and how?
- 3. What types of strategies do you identify and how?
- 4. What is the process for communicating with stakeholders?
- 5. Are there any resources your team uses? (e.g., guidelines, tools) What are the associated costs?

#### **Questions** pertaining to patient involvement

- 1. Do you involve patients in design? If yes, how and how often? How are patients identified?
- 2. Are there any resources your team uses? (e.g., guidelines, tools) What are the associated costs?

#### General questions and business case development

- 1. What percent of CDS do you estimate are considered and never completed in terms of design?
- 2. Please estimate total time for the design process total hours and calendar weeks/months.
- 3. There are multiple reasons for developing CDS. Please estimate the percent of CDS developed to address each of the following:

- a. Risk and patient safety
- b. Financial gain (ROI)c. Government regulations
- d. Quality metrics
- 4. Anything else you'd like to share about the CDS design process?

# Appendix E: Isolated CDS Development Stakeholder Discussion Guide

We are working with the Agency for Healthcare Research and Quality to understand the clinical decision support development process. We would like to better understand things like personnel involved, available resources, and your current processes and workflow. We will conduct semi-structured discussions and ask a series of open ended questions. Examples of questions include:

# Questions pertaining to team makeup

- 1. Who are the folks involved in the CDS development process? What are their disciplines and level of expertise? How were they selected? Is there frequent turnover of developers?
- 2. What is the relationship with EHR vendor developers?
- 3. Is there a formal committee? How often do you meet? What does that meeting look like?

### Questions pertaining to CDS specifications

- 1. How do you evaluate linked knowledge repositories?
- 2. Do you consider internal intra-operability?
- 3. Do you allow for personalization and/or customization?
- 4. Is there a process for error identification and recovery?
- 5. Are there considerations to make alerts more meaningful?
- 6. Are there any resources your team uses? (e.g., subscriptions, guidelines, tools, 3<sup>rd</sup> party vendors) What are the associated costs?

#### **Questions pertaining to user interface**

- 1. What is the process for designing the user interface?
- 2. Are there any resources your team uses? (e.g., subscriptions, guidelines, tools, 3<sup>rd</sup> party vendors) What are the associated costs?

#### **Questions about reuse**

- 1. Are there available/existing resources? (e.g., reference data sets, external pointers, anything that does not need to be built for this project but is relevant/ will be used)
- 2. Can we use components in L1, L2, L3?

#### **Questions about socio-technical challenges?**

- 1. Do you evaluate clinical workflow? How?
- 2. Do you evaluate environmental factors? Organizational factors?
- 3. Is there a process in place for surveillance of similar CDS tools in production? Removal of retired CDS?
- 4. Is there comparison for internal consistency?
- 5. Does the organization consider novel CDS development proprietary? Are there IP considerations?

#### Questions pertaining to stakeholders

- 1. How do you identify stakeholders?
- 2. What types of barriers do you identify and how?
- 3. What types of strategies do you identify and how?
- 4. What is the process for communicating with stakeholders?
- 5. Are there any resources your team uses? (e.g., guidelines, tools) What are the associated costs?

#### **Questions pertaining to testing**

- 1. What is the process for load testing?
- 2. Do you conduct usability testing?
- 3. What is the technical testing process? How are scenarios developed?
- 4. Are there any resources your team uses? (e.g., guidelines, tools) What are the associated costs?

# **General questions**

- 1. What percent of CDS do you estimate are considered and never completed in terms of development?
- 2. Please estimate total time for the development process total hours and calendar weeks/months.
- 3. Anything else you'd like to share about the CDS development process?

# Appendix F: Isolated CDS Deployment Stakeholder Discussion Guide

We are working with the Agency for Healthcare Research and Quality to understand the clinical decision support deployment process. We would like to better understand things like personnel involved, available resources, and your current processes and workflow. We will conduct semi-structured discussions and ask a series of open ended questions. Examples of questions include:

# Questions pertaining to team makeup

- 1. Who are the folks involved in the CDS development process? What are their disciplines and level of expertise? How were they selected?
- 2. Is there a formal committee? How often do you meet? What does that meeting look like?

### Questions pertaining to implementation plan

- 1. Is there a set implementation plan? What does it include?
- 2. Per implementation checklist
  - a. Process to identify skills needed and resource requirements
  - b. Process to identify governance and/or process impact and requirements
  - c. Process to develop implementation plan
  - d. Process to develop evaluation and feedback plan
  - e. Process to develop maintenance and knowledge management plan
- 3. How do you educate staff? Are there new user training opportunities?
- 4. Are there any resources your team uses? (e.g., subscriptions, guidelines, tools, 3<sup>rd</sup> party vendors) What are the associated costs?

### Questions pertaining to evaluation plan

- 1. Is there an evaluation plan? What does it include?
- 2. Is there system-wide reporting? Individual reporting and feedback?

#### Questions pertaining to information services/ information technology support

- 1. Do you predict needs from information services?
- 2. What is the process for hotfixes? Is there a kill switch?
- 3. Is there dedicated upkeep? (e.g., personnel and budget)
- 4. Is there a process to maintain security?

### Questions about socio-technical challenges?

- 1. Do you evaluate clinical workflow? How?
- 2. Do you evaluate environmental factors? Organizational factors?
- 3. Is there a process in place for surveillance of similar CDS tools in production? Removal of retired CDS?

#### Questions pertaining to stakeholders

- 1. How do you identify stakeholders?
- 2. What types of barriers do you identify and how?
- 3. What types of strategies do you identify and how?
- 4. What is the process for communicating with stakeholders?
- 5. Are there any resources your team uses? (e.g., guidelines, tools) What are the associated costs?

# General questions and business case development

- 1. What percent of CDS do you estimate are considered and never completed in terms of deployment?
- 2. Please estimate total time for the deployment process total hours and calendar weeks/months.
- 3. Anything else you'd like to share about the CDS deployment process?

# **Appendix G: Isolated CDS Design Survey (Site 1)**

# CDS Survey – Site 1 Insulin Tool Design (text)

Please complete the survey below. Thank you!

Please estimate the total number of hours you spent on the insulin clinical decision support project.

Please estimate the total number of meetings you attended related to the insulin clinical decision support project.

Please estimate the total number of personnel involved in the insulin clinical decision support project.

Please estimate the total time dedicated to the insulin clinical decision support project (hours).

Please estimate the total calendar time to complete the Design Stage of the insulin clinical decision support project. Please list days, weeks, or months.

Were you involved in the guideline collection process with regards to retrieving evidence? (yes or no)

Please estimate your total time involved in retrieving evidence. (hours)

Did you internally develop guidelines? (yes or no)

Please estimate your total time involved in developing guidelines. (hours)

Were you involved in the reviewing evidence process? (yes or no)

Please estimate your total time involved in reviewing evidence. (hours)

Were you involved in the evidence synthesis process? (yes or no)

Please estimate your total time involved in evidence synthesis process. (hours)

Were you involved in the prioritization of guidelines process? (yes or no)

Please estimate your total time involved in the prioritization of guidelines process. (hours)

Were you involved in the process of determining factors to identify in the record? (yes or no)

Please estimate your total time involved in the process of determining factors to identify in the record. (hours)

Were you involved in the disambiguation of variables process? (yes or no)

Please estimate your total time involved in the disambiguation of variables process. (hours)

Were you involved in the content extraction process? (yes or no)

Please estimate your total time involved in the content extraction process. (hours)

Were you involved in the content clarification process? (yes or no)

Please estimate your total time involved in the content clarification process. (hours)

Were you involved in the content encoding process? (yes or no)

Please estimate your total time involved in the content encoding process. (hours)

Were you involved in the process to determine CDS modality? (yes or no)

Please estimate your total time involved in the process to determine CDS modality. (hours)

Were you involved in the process for reviewing decisions about CDS modality? (yes or no)

Please estimate your total time involved in the process for reviewing decisions about CDS modality. (hours)

Did the CDS Connect artifact provide any resources regarding the determination of CDS modality? (yes or no)

Please estimate the total number of Design Stage iterations.

What methodology do you use in the Design Stage? (e.g. waterfall, scrum)

Please estimate your total time in the Design Stage iteration process. (hours)

Please estimate the team's total time in the Design Stage iteration process. (hours)

Please estimate your total calendar time in the Design Stage iteration process. Please list days, weeks, or months.

Please estimate the team's total calendar time in the Design Stage iteration process. Please list days, weeks, months.

Please describe any resources available to you in the total CDS design process.

Are there any associated software costs (e.g., paid artifacts, support, databases/registries, 3<sup>rd</sup> party vendor)? (yes or no)

Please describe.

Please estimate the associated costs.

Are there any associated hardware costs (e.g., server)? (yes or no)

Please describe.

Please estimate the associated costs.

Are you aware of any additional costs? Anything else you'd like to share about the CDS Design Stage?

# **Appendix H: Isolated CDS Development Survey (Site 1)**

# CDS Survey – Site 1 Insulin Tool Development (text)

Please complete the survey below. Thank you!

Please estimate the total number of hours you spent on the insulin clinical decision support project.

Please estimate the total number of meetings you attended related to the insulin clinical decision support project.

Please estimate the total number of personnel involved in the insulin clinical decision support project.

Please estimate the total time dedicated to the insulin clinical decision support project (hours).

Please estimate the total calendar time to complete the Development Stage of the insulin clinical decision support project. Please list days, weeks, or months.

Were you involved in the process to determine CDS modality with regards to retrieving evidence? (yes or no)

Please estimate your total time involved in the process to determine CDS modality. (hours)

Were you involved in the process for reviewing decisions about CDS modality? (yes or no)

Please estimate your total time involved in the process for reviewing decisions about CDS modality. (hours)

Were you involved in the content extraction process? (yes or no)

Please estimate your total time involved in the content extraction process. (hours)

Were you involved in the content clarification process? (yes or no)

Please estimate your total time involved in the content clarification process. (hours)

Were you involved in the content encoding process? (yes or no)

Please estimate your total time involved in the content encoding process. (hours)

Were you involved in the process of structuring recommendations? (yes or no)

Please estimate your total time involved in the process of structuring recommendations. (hours)

Were you involved in the process of translating and encoding logic flow? (yes or no)

Please estimate your total time involved in the process of translating and encoding logic flow. (hours)

Were you involved in testing and pre-validation? (yes or no)

Please estimate your total time involved in testing and pre-validation. (hours)

Were you involved in local task programming and workflow integration? (yes or no)

Please estimate your total time involved in local task programming and workflow integration. (hours)

Please estimate the total number of Development Stage iterations.

Please describe any resources you used during the CDS development process.

What methodology do you use in the Development Stage? (e.g. waterfall, scrum)

Please estimate your total time in the Development Stage iteration process. (hours)

Please estimate the team's total time in the Development Stage iteration process. (hours)

Please estimate your total calendar time in the Development Stage iteration process. Please list days, weeks, or months.

Please estimate the team's total calendar time in the Development Stage iteration process. Please list days, weeks, months.

Are there any associated software costs (e.g., paid artifacts, support, databases/registries, 3<sup>rd</sup> party vendor)? (yes or no)

Please describe.

Please estimate the associated costs.

Are there any associated hardware costs (e.g., server)? (yes or no)

Please describe.

Please estimate the associated costs.

Are you aware of any additional costs?

Anything else you'd like to share about the CDS Development Stage?

# **Appendix I: Isolated CDS Deployment Survey (Site 1)**

# CDS Survey – Site 1 ERAS Tool Deployment (text)

Please complete the survey below. Thank you!

Please estimate the total number of hours you spent on the ERAS clinical decision support project.

Please estimate the total number of meetings you attended related to the ERAS clinical decision support project.

Please estimate the total number of personnel involved in the ERAS clinical decision support project.

Please estimate the total time dedicated to the ERAS clinical decision support project (hours).

Please estimate the total calendar time to complete the Deployment Stage of the ERAS clinical decision support project. Please list days, weeks, or months.

Were you involved in the usage frequency and impact analysis to identify outcomes process? (yes or no)

Please estimate your total time involved in the usage frequency and impact analysis outcomes process. (hours)

Were you involved in the usage frequency and impact analysis to identify targets process? (yes or no)

Please estimate your total time involved in the usage frequency and impact analysis to identify targets process. (hours)

Were you involved in the usage frequency and impact analysis to set and evaluate goals process? (yes or no)

Please estimate your total time involved in the usage frequency and impact analysis to set and evaluate goals process. (hours)

Were you involved in the vetting process? (yes or no)

Please estimate your total time involved in the vetting process. (hours)

Were you involved in the implementation plan? (yes or no)

Please estimate your total time involved in the implementation plan (hours).

Were you involved in the update and iteration process specifically scheduling? (yes or no)

Please estimate your total time involved in the update and iteration process specifically scheduling. (hours)

Were you involved in the update and iteration process specifically availability of actionable data? (yes or no)

Please estimate your total time involved in the update and iteration process specifically availability of actionable data. (hours)

Were you involved in the update and iteration process specifically vendor updates follow-up? (yes or no)

Please estimate your total time involved in the update and iteration process specifically vendor updates followup. (hours)

Please describe any resources available to you.

Were there any unanticipated events during deployment that were no previously discovered? (yes or no)

Please describe the process that led to identification.

How would you describe the severity of what was discovered? (Cosmetic, minor, major, catastrophic)

Please estimate the duration of the setback?

Please estimate the man hours required to correct the error?

Please estimate the total number of Deployment Stage iterations.

What methodology do you use in the Deployment Stage? (e.g. waterfall, scrum)

Please estimate your total time in the Deployment Stage iteration process. (hours)

Please estimate the team's total time in the Deployment Stage iteration process. (hours)

Please estimate your total calendar time in the Deployment Stage iteration process. Please list days, weeks, or months.

Please estimate the team's total calendar time in the Deployment Stage iteration process. Please list days, weeks, months.

Are there any associated software costs (e.g., paid artifacts, support, databases/registries, 3<sup>rd</sup> party vendor)? (yes or no)

Please describe.

Please estimate the associated costs.

Are there any associated hardware costs (e.g., server)? (yes or no)

Please describe.

Please estimate the associated costs.

Are you aware of any additional costs?

Anything else you'd like to share about the CDS Deployment Stage?

# **Appendix J: Isolated CDS Design Survey (Site 2)**

# CDS Survey – Site 2 Lead Tool Design (text)

Please complete the survey below. Thank you!

Please estimate the total number of hours you spent on the lead clinical decision support project.

Please estimate the total number of meetings you attended related to the lead clinical decision support project.

Please estimate the total number of personnel involved in the lead clinical decision support project.

Please estimate the total time dedicated to the lead clinical decision support project (hours).

Please estimate the total calendar time to complete the Design Stage of the lead clinical decision support project. Please list days, weeks, or months.

Were you involved in the guideline collection process with regards to retrieving evidence? (yes or no)

Please estimate your total time involved in retrieving evidence. (hours)

Did you internally develop guidelines? (yes or no)

Please estimate your total time involved in developing guidelines. (hours)

Were you involved in the reviewing evidence process? (yes or no)

Please estimate your total time involved in reviewing evidence. (hours)

Were you involved in the evidence synthesis process? (yes or no)

Please estimate your total time involved in evidence synthesis process. (hours)

Were you involved in the prioritization of guidelines process? (yes or no)

Please estimate your total time involved in the prioritization of guidelines process. (hours)

Were you involved in the process of determining factors to identify in the record? (yes or no)

Please estimate your total time involved in the process of determining factors to identify in the record. (hours)

Were you involved in the disambiguation of variables process? (yes or no)

Please estimate your total time involved in the process of determining factors to identify in the record. (hours)

Were you involved in the content extraction process? (yes or no)

Please estimate your total time involved in the content extraction process. (hours)

Were you involved in the content clarification process? (yes or no)

Please estimate your total time involved in the content clarification process. (hours)

Were you involved in the content encoding process? (yes or no)

Please estimate your total time involved in the content encoding process. (hours)

Were you involved in the process to determine CDS modality? (yes or no)

Please estimate your total time involved in the process to determine CDS modality. (hours)

Please estimate the total number of Design Stage iterations.

What methodology do you use in the Design Stage? (e.g. waterfall, scrum)

Please estimate your total time in the Design Stage iteration process. (hours)

Please estimate the team's total time in the Design Stage iteration process. (hours)

Please estimate your total calendar time in the Design Stage iteration process. Please list days, weeks, or months.

Please estimate the team's total calendar time in the Design Stage iteration process. Please list days, weeks, months.

Please describe any resources available to you in the total CDS design process.

Are there any associated software costs (e.g., paid artifacts, support, databases/registries, 3<sup>rd</sup> party vendor)? (yes or no)

Please describe.

Please estimate the associated costs.

Are there any associated hardware costs (e.g., server)? (yes or no)

Please describe.

Please estimate the associated costs.

Are you aware of any additional costs?

Anything else you'd like to share about the CDS Design Stage?

# **Appendix K: Isolated CDS Development Survey (Site 2)**

# CDS Survey - Site 2 Lead Tool Development (text)

Please complete the survey below. Thank you!

Please estimate the total number of hours you spent on the lead clinical decision support project.

Please estimate the total number of meetings you attended related to the lead clinical decision support project.

Please estimate the total number of personnel involved in the lead clinical decision support project.

Please estimate the total time dedicated to the lead clinical decision support project (hours).

Please estimate the total calendar time to complete the Development Stage of the lead clinical decision support project. Please list days, weeks, or months.

Were you involved in the process to determine CDS modality with regards to retrieving evidence? (yes or no)

Please estimate your total time involved in the process to determine CDS modality. (hours)

Were you involved in the process for reviewing decisions about CDS modality? (yes or no)

Please estimate your total time involved in the process for reviewing decisions about CDS modality. (hours)

Were you involved in the content extraction process? (yes or no)

Please estimate your total time involved in the content extraction process. (hours)

Were you involved in the content clarification process? (yes or no)

Please estimate your total time involved in the content clarification process. (hours)

Were you involved in the content encoding process? (yes or no)

Please estimate your total time involved in the content encoding process. (hours)

Were you involved in the process of structuring recommendations? (yes or no)

Please estimate your total time involved in the process of structuring recommendations. (hours)

Were you involved in the process of structuring recommendations? (yes or no)

Please estimate your total time involved in the process of structuring recommendations. (hours)

Were you involved in the process of translating and encoding logic flow? (yes or no)

Please estimate your total time involved in the process of translating and encoding logic flow. (hours)

Were you involved in testing and pre-validation? (yes or no)

Please estimate your total time involved in testing and pre-validation. (hours)

Were you involved in local task programming and workflow integration? (yes or no)

Please estimate your total time involved in local task programming and workflow integration. (hours)

Please estimate the total number of Development Stage iterations.

Please describe any resources you used during the CDS development process.

What methodology do you use in the Development Stage? (e.g. waterfall, scrum)

Please estimate your total time in the Development Stage iteration process. (hours)

Please estimate the team's total time in the Development Stage iteration process. (hours)

Please estimate your total calendar time in the Development Stage iteration process. Please list days, weeks, or months.

Please estimate the team's total calendar time in the Development Stage iteration process. Please list days, weeks, months.

Are there any associated software costs (e.g., paid artifacts, support, databases/registries, 3<sup>rd</sup> party vendor)? (yes or no)

Please describe.

Please estimate the associated costs.

Are there any associated hardware costs (e.g., server)? (yes or no)

Please describe.

Please estimate the associated costs.

Are you aware of any additional costs?

Anything else you'd like to share about the CDS Development Stage?

# **Appendix L: Isolated CDS Deployment Survey (Site 2)**

# CDS Survey - Site 2 Lead Tool Deployment (text)

Please complete the survey below. Thank you!

Please estimate the total number of hours you spent on the lead clinical decision support project.

Please estimate the total number of meetings you attended related to the lead clinical decision support project.

Please estimate the total number of personnel involved in the lead clinical decision support project.

Please estimate the total time dedicated to the lead clinical decision support project (hours).

Please estimate the total calendar time to complete the Deployment Stage of the lead clinical decision support project. Please list days, weeks, or months.

Were you involved in the usage frequency and impact analysis to identify outcomes process? (yes or no)

Please estimate your total time involved in the usage frequency and impact analysis outcomes process. (hours)

Were you involved in the usage frequency and impact analysis to identify targets process? (yes or no)

Please estimate your total time involved in the usage frequency and impact analysis to identify targets process. (hours)

Were you involved in the usage frequency and impact analysis to set and evaluate goals process? (yes or no)

Please estimate your total time involved in the usage frequency and impact analysis to set and evaluate goals process. (hours)

Were you involved in the vetting process? (yes or no)

Please estimate your total time involved in the vetting process. (hours)

Were you involved in the implementation plan? (yes or no)

Please estimate your total time involved in the implementation plan (hours).

Were you involved in the update and iteration process specifically scheduling? (yes or no)

Please estimate your total time involved in the update and iteration process specifically scheduling. (hours)

Were you involved in the update and iteration process specifically availability of actionable data? (yes or no)

Please estimate your total time involved in the update and iteration process specifically availability of actionable data. (hours)

Were you involved in the update and iteration process specifically vendor updates follow-up? (yes or no)

Please estimate your total time involved in the update and iteration process specifically vendor updates follow-up. (hours)

Please describe any resources available to you.

Were there any unanticipated events during deployment that were no previously discovered? (yes or no)

Please describe the process that led to identification.

How would you describe the severity of what was discovered? (Cosmetic, minor, major, catastrophic)

Please estimate the duration of the setback?

Please estimate the man hours required to correct the error?

Please estimate the total number of Deployment Stage iterations.

What methodology do you use in the Deployment Stage? (e.g. waterfall, scrum)

Please estimate your total time in the Deployment Stage iteration process. (hours)

Please estimate the team's total time in the Deployment Stage iteration process. (hours)

Please estimate your total calendar time in the Deployment Stage iteration process. Please list days, weeks, or months.

Please estimate the team's total calendar time in the Deployment Stage iteration process. Please list days, weeks, months.

Are there any associated software costs (e.g., paid artifacts, support, databases/registries, 3<sup>rd</sup> party vendor)? (yes or no)

Please describe.

Please estimate the associated costs.

Are there any associated hardware costs (e.g., server)? (yes or no)

Please describe.

Please estimate the associated costs.

Are you aware of any additional costs?

Anything else you'd like to share about the CDS Deployment Stage?

# Appendix M: Shareable CDS Design Stakeholder Discussion Guide

### Questions pertaining to team makeup

- 1. Are the same people involved in the shareable CDS design process as the traditional CDS design process? What are their disciplines and level of expertise? How were they selected?
- 2. What does the committee involvement look regarding CDS shareable design? What does that meeting look like?

#### **Questions pertaining to CDS specifications**

- 1. Did you use the clinical condition as defined by the inclusions in the artifact? If not, how did you define the clinical condition?
- 2. Did the CDS Connect artifact help you define the clinical user? If so, how?
- 3. Did you use the patient population as defined by the artifact? If not, how did you define the patient population?
- 4. Did the CDS Connect artifact help you determine the percent of the population to be impacted? If so, how?
- 5. Did the CDS Connect artifact help you define desired patient outcomes? If so, how?
- 6. Did the CDS Connect artifact help you define organizational outcomes? If so, how?
- 7. Did the CDS Connect artifact help you discuss the integration of quality measures? If so, how?
- 8. Did the CDS Connect artifact help you identify potential outliers? If so, how?
- 9. Did you use the CDS modality as defined by the artifact? If not, how did you determine CDS modality?
- 10. Did the CDS Connect artifact help you develop scenarios? If so, how?
- 11. Did the CDS Connect artifact help you modify thresholds? If so, how?
- 12. Did the CDS Connect artifact help you with error identification and recovery? If so, how?
- 13. Are there any resources your team used outside of the CDS Connect platform in the shareable CDS design process (e.g., subscriptions, guidelines, tools, 3<sup>rd</sup> party vendors)? What are the associated costs?

### Questions pertaining to guideline selection

- 1. How did you use the guidelines provided in the CDS Connect artifact?
- 2. Are there any resources your team used for guideline selection outside of the CDS Connect platform in the shareable CDS design process? What are the associated costs?

#### Questions about socio-technical factors

- 1. Does use of the CDS Connect artifact change how you evaluate clinical workflow? How?
- 2. Does use of the CDS Connect artifact change how you evaluate environmental factors? Organizational factors?
- 3. How did you perform surveillance of similar CDS tools in production using the CDS Connect artifact? Removal of retired CDS?
- 4. What was the process to make this tool make using the shareable CDS artifact consistent with other internal tools?
- 5. What is the organization's perspective on the IP of this tool made using the shareable CDS artifact?

#### **Questions pertaining to stakeholders**

- 1. Did the CDS Connect artifact help you identify stakeholders?
- 2. What barriers were encountered during the shareable CDS design process?
- 3. What strategies were used to localize the CDS Connect artifact to your site?
- 4. Are there any resources your team used regarding stakeholders outside of the CDS Connect platform in the shareable CDS design process (e.g., guidelines, tools)? What are the associated costs?

#### **Questions** pertaining to patient involvement

1. Did you involve patients in shareable CDS design process? If yes, how and how often? How are patients identified?

2. Are there any resources your team used regarding patient involvement outside of the CDS Connect platform in the shareable CDS design process (e.g., guidelines, tools)? What are the associated costs?

### General questions and business case development

- 1. Please estimate total time for the shareable CDS design process total hours and calendar weeks/months.
- 2. Did you require assistance or seek information from resources outside of the CDS Connect artifact, including external websites, developers of the CDS artifact, other users of the artifact or other "outside" sources of information? If so briefly explain what resource was used, what information was gained and why you chose to seek additional information.
- 3. What factors went into your organization's selection of this shareable CDS artifact?
- 4. Overall, how is the shareable CDS design process different than the traditional CDS design process?
- 5. Would you use the CDS Connect platform in the future? Why?
- 6. Anything else you'd like to share about the shareable CDS design process?

# Appendix N: Shareable CDS Development Stakeholder Discussion Guide

### Questions pertaining to team makeup

- 1. Are the same people involved in the shareable CDS development process as the traditional CDS development process? What are their disciplines and level of expertise? How were they selected? Is there frequent turnover of developers?
- 2. Does the relationship with EHR vendor developers change when using the CDS Connect artifact?
- 3. What does committee involvement look like regarding the CDS shareable development process? How often do you meet? What does that meeting look like?

### Questions pertaining to CDS specifications

- 1. How does evaluation of linked knowledge repositories change when using the CDS Connect artifact?
- 2. How does consideration of internal intra-operability change when using the CDS Connect artifact?
- 3. How does personalization and/or customization of the build differ when using the CDS Connect artifact?
- 4. Did the CDS Connect artifact help you with error identification and recovery? If so, how?
- 5. Did the CDS Connect artifact help you make alerts more meaningful? If so, how?
- 6. Are there any resources your team used outside of the CDS Connect platform in the shareable CDS development process (e.g., subscriptions, guidelines, tools, 3<sup>rd</sup> party vendors)? What are the associated costs?

#### Questions pertaining to user interface

- 1. How does the process for designing the user interface change when using the CDS Connect artifact?
- 2. In the shareable CDS development process, are there any resources your team used for the developing the user interface outside of the CDS Connect platform (e.g., subscriptions, guidelines, tools, 3<sup>rd</sup> party vendors)? What are the associated costs?

#### **Ouestions about reuse**

- 1. Are there available/existing resources outside of the CDS Connect platform? If so, are they used in the shareable CDS development process (e.g., reference data sets, external pointers, anything that does not need to be built for this project but is relevant/ will be used)?
- 2. Can we use components in L1, L2, L3?

#### Questions about socio-technical challenges

- 1. Does use of the CDS Connect artifact change how you evaluate clinical workflow? How?
- 2. Does use of the CDS Connect artifact change how you evaluate environmental factors? Organizational factors?
- 3. How did you perform surveillance of similar CDS tools in production using the CDS Connect artifact? Removal of retired CDS?
- 4. What was the process to make this tool make using the shareable CDS artifact consistent with other internal tools?
- 5. What is the organization's perspective on the IP of this tool made using the shareable CDS artifact?

# Questions pertaining to stakeholders

- 1. Did the CDS Connect artifact help you identify stakeholders?
- 2. What barriers were encountered during the shareable CDS design process?
- 3. What strategies were used to localize the CDS Connect artifact to your site?
- 4. Did the process for communicating with stakeholders change when using the CDS Connect artifact? If so, how?
- 5. In the shareable CDS development process, are there any resources your team used regarding stakeholders outside of the CDS Connect platform? (e.g., guidelines, tools) What are the associated costs?

# **Questions pertaining to testing**

- 1. Did the process for load testing change when using the CDS Connect artifact? If so, how?
- 2. Do you conduct usability testing when using the CDS Connect artifact? If so, how did it change?
- 3. Did the technical testing process change when using the CDS Connect artifact? How are scenarios developed?
- 4. Are there any resources your team used regarding testing outside of the CDS Connect platform (e.g., guidelines, tools)? What are the associated costs?

### **General questions**

- 1. Would the percentage of CDS considered and never completed in terms of development change when using the CDS Connect platform?
- 2. Did you require assistance or seek information from resources outside of the CDS Connect artifact, including external websites, developers of the CDS artifact, other users of the artifact or other "outside" sources of information? If so briefly explain what resource was used, what information was gained and why you chose to seek additional information.
- 3. Overall, how is the shareable CDS development process different than the traditional CDS development process?
- 4. Please estimate total time for the shareable CDS development process total hours and calendar weeks/months.
- 5. Would you like to use the CDS Connect platform in the future? Why?
- 6. Anything else you'd like to share about the shareable CDS development process?

# **Appendix O: Shareable CDS Deployment Stakeholder Discussion Guide**

### Questions pertaining to team makeup

- 1. Are (or would) the same people involved in the shareable CDS deployment process as the traditional CDS design process? What are their disciplines and level of expertise? How were they selected?
- 2. What does the committee involvement look regarding CDS shareable deployment? What does that meeting look like?

#### Questions pertaining to implementation plan

- 1. Did/would you use the set implementation plan provided in the CDS Connect artifact? What does it include?
- 2. Per implementation checklist
  - a. Does the CDS artifact provide a process to identify skills needed and resource requirements? Did/would you use it?
  - b. Does the CDS artifact provide a process to identify governance and/or process impact and requirements? Did/would you use it?
  - c. Does the CDS artifact provide a process to develop implementation plan? Did/would you use it?
  - d. Does the CDS artifact provide a process to develop evaluation and feedback plan? Did/would you use it?
  - e. Does the CDS artifact provide a process to develop maintenance and knowledge management plan? Did/would you use it?
- 3. Are resources provided in the CDS Connect artifact educate staff about the deployment of this shareable CDS tool? Did/would you use them?
- 4. Are there any resources your team used/would use outside of the CDS Connect platform in the shareable CDS deployment process (e.g., subscriptions, guidelines, tools, 3<sup>rd</sup> party vendors)? What are the associated costs?

### Questions pertaining to evaluation plan

- 1. Is there an evaluation plan provided in the CDS artifact? What does it include?
- 2. Does system-wide reporting differ regarding deployment of a shareable CDS tool? Individual reporting and feedback?

#### Questions pertaining to information services/ information technology support

- 1. Does the CDS Connect artifact provide resources to assist with predicting needs from information services?
- 2. Does the CDS Connect artifact provide resources to assist with upkeep?
- 3. Does the CDS Connect artifact provide resources to assist with maintaining security?

#### Questions about socio-technical challenges

- 1. Does use of the CDS Connect artifact change how you evaluate clinical workflow with regard to CDS deployment? How?
- 2. Does use of the CDS Connect artifact change how you evaluate environmental factors? Organizational factors?
- 3. How did you perform surveillance of similar CDS tools in production using the CDS Connect artifact? Removal of retired CDS?

#### Questions pertaining to stakeholders

- 1. Did the CDS Connect artifact help you identify stakeholders?
- 2. What barriers were encountered during the shareable CDS deployment process?
- 3. What strategies were used to localize the CDS Connect artifact to your site?
- 4. Does use of the CDS Connect artifact change how you communicate with stakeholders?

5. Are there any resources your team used regarding stakeholders outside of the CDS Connect platform in the shareable CDS design process? (e.g., guidelines, tools) What are the associated costs?

### General questions and business case development

- 1. Please estimate total time for the shareable CDS deployment process total hours and calendar weeks/months.
- 2. Did you require assistance or seek information from resources outside of the CDS Connect artifact, including external websites, developers of the CDS artifact, other users of the artifact or other "outside" sources of information? If so briefly explain what resource was used, what information was gained and why you chose to seek additional information.
- 3. Overall, how is the shareable CDS deployment process different than the traditional CDS deployment process?
- 4. Would you use the CDS Connect platform in the future? Why?
- 5. Anything else you'd like to share about the shareable CDS deployment process?

# **Appendix P: Shareable CDS Design Survey**

# CDS Survey - Shareable Design (text)

Please complete the survey below. Thank you!

Please estimate the total number of hours you spent on the insulin clinical decision support project.

Please estimate the total number of meetings you attended related to the insulin clinical decision support project.

Please estimate the total number of personnel involved in the insulin clinical decision support project.

Please estimate the total time dedicated to the insulin clinical decision support project (hours).

Please estimate the total calendar time to complete the shareable Design Stage of the insulin clinical decision support project. Please list days, weeks, or months.

Were you involved in the guideline collection process with regards to retrieving evidence? (yes or no)

Please estimate your total time involved in retrieving evidence. (hours)

Did the CDS Connect artifact provide any resources regarding the retrieval of evidence? (yes or no)

Did you internally develop guidelines? (yes or no)

Please estimate your total time involved in developing guidelines. (hours)

Did the CDS Connect artifact provide any resources regarding the development of guidelines? (yes or no)

Were you involved in the reviewing evidence process? (yes or no)

Please estimate your total time involved in reviewing evidence. (hours)

Did the CDS Connect artifact provide any resources regarding the review of evidence? (yes or no)

Were you involved in the evidence synthesis process? (yes or no)

Please estimate your total time involved in evidence synthesis process. (hours)

Did the CDS Connect artifact provide any resources regarding the synthesis evidence? (yes or no)

Were you involved in the prioritization of guidelines process? (yes or no)

Please estimate your total time involved in the prioritization of guidelines process. (hours)

Did the CDS Connect artifact provide any resources regarding the prioritization of guidelines? (yes or no)

Were you involved in the process of determining factors to identify in the record? (yes or no)

Please estimate your total time involved in the process of determining factors to identify in the record. (hours)

Did the CDS Connect artifact provide any resources regarding the prioritization of guidelines? (yes or no)

Were you involved in the process of determining factors to identify in the record? (yes or no)

Please estimate your total time involved in the process of determining factors to identify in the record. (hours)

Did the CDS Connect artifact provide any resources regarding the determination of factors? (yes or no)

Were you involved in the disambiguation of variables process? (yes or no)

Please estimate your total time involved in the disambiguation of variables process. (hours)

Did the CDS Connect artifact provide any resources regarding the disambiguation of variables process? (yes or no)

Were you involved in the content extraction process? (yes or no)

Please estimate your total time involved in the content extraction process. (hours)

Did the CDS Connect artifact provide any resources regarding the content extraction process? (yes or no)

Were you involved in the content clarification process? (yes or no)

Please estimate your total time involved in the content clarification process. (hours)

Did the CDS Connect artifact provide any resources regarding the content clarification process? (yes or no)

Were you involved in the content encoding process? (yes or no)

Please estimate your total time involved in the content encoding process. (hours)

Did the CDS Connect artifact provide any resources regarding the content encoding process? (yes or no)

Were you involved in the process to determine CDS modality? (yes or no)

Please estimate your total time involved in the process to determine CDS modality. (hours)

Did the CDS Connect artifact provide any resources regarding the determination of CDS modality? (yes or no)

Were you involved in the process for reviewing decisions about CDS modality? (yes or no)

Please estimate your total time involved in the process for reviewing decisions about CDS modality. (hours)

Did the CDS Connect artifact provide any resources regarding the review of decisions about CDS modality? (yes or no)

Please estimate the total number of shareable Design Stage iterations.

What methodology do you use in the shareable Design Stage? (e.g. waterfall, scrum)

Please estimate your total time in the shareable Design Stage iteration process. (hours)

Please estimate the team's total time in the shareable Design Stage iteration process. (hours)

Please estimate your total calendar time in the shareable Design Stage iteration process. Please list days, weeks, or months.

Please estimate the team's total calendar time in the shareable Design Stage iteration process. Please list days, weeks, months.

Please describe any resources available to you in the shareable CDS design process.

Are there any associated software costs (e.g., paid artifacts, support, databases/registries, 3<sup>rd</sup> party vendor)? (yes or no)

Please describe.

Please estimate the associated costs.

Are there any associated hardware costs (e.g., server)? (yes or no)

Please describe.

Please estimate the associated costs.

Are you aware of any additional costs?

Anything else you'd like to share about the shareable CDS Design Stage?

Is there anything else you'd like to share about the use of CDS Connect artifacts?

Would you use the CDS Connect platform again?

# **Appendix Q: Shareable CDS Development Survey**

# **CDS Survey – Shareable Development (text)**

Please complete the survey below. Thank you!

Please estimate the total number of hours you spent on the clinical decision support project.

Please estimate the total number of meetings you attended related to the clinical decision support project.

Please estimate the total number of personnel involved in the clinical decision support project.

Please estimate the total time dedicated to the clinical decision support project (hours).

Please estimate the total calendar time to complete the shareable Development Stage of the insulin clinical decision support project. Please list days, weeks, or months.

Were you involved in the process to determine CDS modality with regards to retrieving evidence? (yes or no)

Please estimate your total time involved in the process to determine CDS modality. (hours)

Did the CDS Connect artifact provide any resources regarding the retrieval of evidence to determine CDS modality? (yes or no)

Were you involved in the process for reviewing decisions about CDS modality? (yes or no)

Please estimate your total time involved in the process for reviewing decisions about CDS modality. (hours)

Did the CDS Connect artifact provide any resources regarding the review of decisions about CDS modality? (yes or no)

Were you involved in the content extraction process? (yes or no)

Please estimate your total time involved in the content extraction process. (hours)

Did the CDS Connect artifact provide any resources regarding content extraction? (yes or no)

Were you involved in the content clarification process? (yes or no)

Please estimate your total time involved in the content clarification process. (hours)

Did the CDS Connect artifact provide any resources regarding content clarification? (yes or no)

Were you involved in the content encoding process? (yes or no)

Please estimate your total time involved in the content encoding process. (hours)

Did the CDS Connect artifact provide any resources regarding the content encoding process? (yes or no)

Were you involved in the process of structuring recommendations? (yes or no)

Please estimate your total time involved in the process of structuring recommendations. (hours)

Did the CDS Connect artifact provide any resources regarding the structuring of recommendations? (yes or no)

Were you involved in the process of translating and encoding logic flow? (yes or no)

Please estimate your total time involved in the process of translating and encoding logic flow. (hours)

Did the CDS Connect artifact provide any resources regarding the translating and encoding of logic flow? (yes or no)

Were you involved in testing and pre-validation? (yes or no)

Please estimate your total time involved in testing and pre-validation. (hours)

Did the CDS Connect artifact provide any resources regarding testing and pre-validation? (yes or no)

Were you involved in local task programming and workflow integration? (yes or no)

Please estimate your total time involved in local task programming and workflow integration. (hours)

Did the CDS Connect artifact provide any resources regarding programming and workflow integration? (yes or no)

Please estimate the total number of shareable Development Stage iterations.

Please describe any resources you used during the shareable CDS development process.

What methodology do you use in the shareable Development Stage? (e.g. waterfall, scrum)

Please estimate your total time in the shareable Development Stage iteration process, (hours)

Please estimate the team's total time in the shareable Development Stage iteration process. (hours)

Please estimate your total calendar time in the shareable Development Stage iteration process. Please list days, weeks, or months.

Please estimate the team's total calendar time in the shareable Development Stage iteration process. Please list days, weeks, months.

Are there any associated software costs (e.g., paid artifacts, support, databases/registries, 3<sup>rd</sup> party vendor)? (yes or no)

Please describe.

Please estimate the associated costs.

Are there any associated hardware costs (e.g., server)? (yes or no)

Please describe.

Please estimate the associated costs.

Are you aware of any additional costs?

Anything else you'd like to share about the shareable CDS Development Stage?

Anything else you'd like to share about using the CDS artifact?

Would you use the CDS Connect platform again?

# **Appendix R: Shareable CDS Deployment Survey**

# **CDS Survey – Shareable Deployment (text)**

Please complete the survey below. Thank you!

Please estimate the total number of hours you spent on the clinical decision support project.

Please estimate the total number of meetings you attended related to the clinical decision support project.

Please estimate the total number of personnel involved in the clinical decision support project.

Please estimate the total time dedicated to the clinical decision support project (hours).

Please estimate the total calendar time to complete the Deployment Stage of the clinical decision support project. Please list days, weeks, or months.

Were you involved in the usage frequency and impact analysis to identify outcomes process? (yes or no)

Did the CDS Connect artifact provide any resources regarding usage frequency and impact analysis to identify outcomes? (yes or no)

Please estimate your total time involved in the usage frequency and impact analysis outcomes process. (hours)

Were you involved in the usage frequency and impact analysis to identify targets process? (yes or no)

Did the CDS Connect artifact provide any resources regarding usage frequency and impact analysis to identify targets? (yes or no)

Please estimate your total time involved in the usage frequency and impact analysis to identify targets process. (hours)

Were you involved in the usage frequency and impact analysis to set and evaluate goals process? (yes or no)

Did the CDS Connect artifact provide any resources regarding usage frequency and impact analysis to set and evaluate goals process? (yes or no)

Please estimate your total time involved in the usage frequency and impact analysis to set and evaluate goals process. (hours)

Were you involved in the vetting process? (yes or no)

Did the CDS Connect artifact provide any resources regarding the vetting process? (yes or no)

Please estimate your total time involved in the vetting process. (hours)

Were you involved in the implementation plan? (yes or no)

Did the CDS Connect artifact provide any resources regarding the implementation plan? (yes or no)

Please estimate your total time involved in the implementation plan (hours).

Were you involved in the update and iteration process specifically scheduling? (yes or no)

Did the CDS Connect artifact provide any resources regarding the update and iteration process specifically scheduling? (yes or no)

Please estimate your total time involved in the update and iteration process specifically scheduling. (hours)

Were you involved in the update and iteration process specifically availability of actionable data? (yes or no)

Did the CDS Connect artifact provide any resources regarding the update and iteration process specifically availability of actionable data? (yes or no)

Please estimate your total time involved in the update and iteration process specifically availability of actionable data. (hours)

Were you involved in the update and iteration process specifically vendor updates follow-up? (yes or no)

Did the CDS Connect artifact provide any resources regarding the update and iteration process specifically vendor updates follow-up? (yes or no)

Please estimate your total time involved in the update and iteration process specifically vendor updates follow-up. (hours)

Please describe any resources available to you on the CDS Connect artifact for the shareable CDS deployment process.

Please describe any resources available to you in the shareable CDS deployment process outside of the CDS Connect artifact.

Were there any unanticipated events during deployment that were no previously discovered? (yes or no) Please describe the process that led to identification.

How would you describe the severity of what was discovered? (Cosmetic, minor, major, catastrophic)

Please estimate the duration of the setback?

Please estimate the man hours required to correct the error?

Please estimate the total number of shareable Deployment Stage iterations.

What methodology do you use in the shareable Deployment Stage? (e.g. waterfall, scrum)

Please estimate your total time in the shareable Deployment Stage iteration process. (hours)

Please estimate the team's total time in the shareable Deployment Stage iteration process. (hours)

Please estimate your total calendar time in the shareable Deployment Stage iteration process. Please list days, weeks, or months.

Please estimate the team's total calendar time in the shareable Deployment Stage iteration process. Please list days, weeks, months.

Are there any associated software costs (e.g., paid artifacts, support, databases/registries, 3<sup>rd</sup> party vendor)? (yes or no)

Please describe.

Please estimate the associated costs.

Are there any associated hardware costs (e.g., server)? (yes or no)

Please describe.

Please estimate the associated costs.

Are you aware of any additional costs?

# **Appendix S: CDS Business Case Development Discussion Guide**

#### **Choosing leadership:**

- 1. What types of leadership roles (e.g., CMIOs, CMOs) are involved in decisions surrounding use of shareable CDS/shareable HIT in your organization? What does involvement look like (e.g., committee memberships)?
- 2. What is the process of identifying the types of leadership expertise you will require on use of shareable CDS/shareable HIT projects in your organization?
- 3. At what stages of the shareable CDS lifecycle/shareable HIT (idea creation, content development, surveillance, design, development, deployment) do organization leadership usually become involved?
- 4. Does your organization have avenues to apply lessons learned from shareable CDS implementations about outcomes or effectiveness measures to facilitate future CDS implementation efforts?

### The management case – is this achievable?

- 1. How do you determine whether shareable CDS/shareable HIT projects are achievable?
- 2. Who defines factors comprising achievability? How long does it take to calculate achievability?
- 3. What stages of the shareable CDS/shareable HIT lifecycle (idea creation, content development, surveillance, design, development, deployment) are these decisions made?
- 4. What are costs/benefits that you consider during management case development?
- 5. What is the time scale for establishing achievability of shareable CDS/shareable HIT?
- 6. Does using a repository of shareable CDS resources in your site's workflow appear to be achievable? Why or why not? Consider submitting or implementation of resources?
- 7. Do you periodically re-evaluate the achievability of using a repository of shareable CDS resources and/or developing shareable CDS/shareable HIT? If yes, what triggers the re-evaluation?
- 8. How do external factors such as marketplace, policy, legal, and governance issue affect the use of shareable CDS/shareable HIT?

#### The strategic case – is there a compelling case for change?

- 1. How would you determine whether shareable CDS/shareable HIT meets the investment objectives, business needs, and service requirements of the organization?
- 2. How would you determine whether the shareable CDS/shareable HIT fits with the broader strategies, programs, and projects of the organization?
- 3. Who defines factors that comprise the strategic case for shareable CDS/shareable HIT? How long does it take to calculate the strategic case?
- 4. What are costs/benefits that you consider during strategic case development for shareable CDS?
- 5. Does a repository of shareable CDS resources appear to be strategically viable? Why or why not? If not, can you provide some insight on how to make it viable?
- 6. Do you periodically re-evaluate whether the shareable CDS meets organizational needs? If yes, when or what triggers the re-evaluation?
- 7. How do factors such as the marketplace, policy, legal issues, interoperability, and governance affect the strategic case for CDS?

#### The economic case – how do you optimize value for money?

- 1. How would you determine whether shareable CDS/shareable HIT offers value for money in terms of economy, efficiency, and effectiveness?
- 2. Who defines factors that ensure optimizing value for money for shareable CDS/shareable HIT? How long does it take to calculate the economic case?
- 3. At what stages of the shareable CDS/shareable HIT lifecycle (idea creation, content development, surveillance, design, development, deployment) are these decisions made?
- 4. What are costs/benefits that you consider during economic case development?

- 5. What is the time scale for establishing economic viability of shareable CDS/shareable HIT?
- 6. Does a repository of shareable CDS resources appear to be economically viable? Why or why not?
- 7. Do you periodically re-evaluate the economic case? If yes, what triggers the re-evaluation?
- 8. How do factors such as the marketplace, policy, legal issues, and governance affect the economic case for shareable CDS/shareable HIT?

#### The commercial case – is this commercially viable?

- 1. How do you determine whether shareable CDS/shareable HIT offers commercial viability?
- 2. Who defines factors comprising commercial viability? How long does it take to calculate commercial viability?
- 3. What stages of the shareable CDS lifecycle/shareable HIT (idea creation, content development, surveillance, design, development, deployment) are these decisions made?
- 4. What are costs/benefits that you consider during economic case development?
- 5. What is the time scale for establishing commercial viability of CDS Connect/shareable CDS/shareable HIT?
- 6. Does repository of shareable CDS resources appear to be commercially viable? Why or why not?
- 7. Do you periodically re-evaluate the commercial viability of projects? If yes, what triggers the re-evaluation?
- 8. How do external factors such as marketplace, policy, legal, and governance issue affect the commercial case for shareable CDS/shareable HIT?

#### The financial case – is this financially affordable?

- 1. How do you determine whether shareable CDS/shareable HIT is financially affordable?
- 2. Who defines factors comprising financial affordability? How long does it take to calculate financial affordability?
- 3. What stages of the shareable CDS/shareable HIT lifecycle (idea creation, content development, surveillance, design, development, deployment) are these decisions made?
- 4. What are costs/benefits that you consider during financial case development?
- 5. What is the time scale for establishing financial affordability viability of CDS?
- 6. Does a repository of shareable CDS resources appear to be financially affordable? Why or why not?
- 7. Do you periodically re-evaluate the financial affordability of shareable CDS/shareable HIT? If yes, what triggers the re-evaluation?
- 8. How do external factors such as marketplace, policy, legal, and governance issue affect the financial case for a repository of shareable CDS resources?